

ASTRAZENECA PLC  
Form 6-K  
January 07, 2010

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For December 2009

Commission File Number: 001-11960

AstraZeneca PLC

15 Stanhope Gate, London W1K 1LN, England

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

AstraZeneca PLC

INDEX TO EXHIBITS

1. Press release entitled, “Transparency Directive Voting Rights and Capital”, dated 1 December 2009.
  2. Press release entitled, “AstraZeneca and Targacept form global collaboration and licence agreement for late-stage investigational product TC-5214 for the treatment of Major Depressive Disorder”, dated 3 December 2009.
  3. Press release entitled, “USA FDA approves SEROQUEL XR for add-on treatment of Major Depressive Disorder”, dated 4 December 2009.
  4. Press release entitled, “TR-1: Notification of Major Interest in Shares”, dated 8 December 2009.
  5. Press release entitled, “Advisory Committee briefing materials for CRESTOR sNDA available on US FDA web site”, dated 11 December 2009.
  6. Press release entitled, “Favourable vote from FDA Advisory Committee on benefit / risk of CRESTOR in JUPITER study”, dated 16 December 2009.
  7. Press release entitled, “AstraZeneca to acquire infection research company Novoxel and expand collaboration with Forest Laboratories”, dated 23 December 2009.
  8. Press release entitled, “MedImmune replies to FDA complete response letter on Motavizumab”, dated 24 December 2009.
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 5 January 2010

By: /s/ J Hoskins  
Name: Justin Hoskins  
Title: Deputy Company Secretary

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Item 1

Transparency Directive  
Voting Rights and Capital

The following notification is made in accordance with the UK Financial Services Authority Disclosure and Transparency Rule 5.6.1. On 30 November 2009 the issued share capital of AstraZeneca PLC with voting rights is 1,450,012,739 ordinary shares of US\$0.25. No shares are held in Treasury. Therefore, the total number of voting rights in AstraZeneca PLC is 1,450,012,739.

The above figure for the total number of voting rights may be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their interest in, or a change to their interest in, AstraZeneca PLC under the FSA's Disclosure and Transparency Rules.

A C N Kemp  
Company Secretary  
1 December 2009

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Item 2

ASTRAZENECA AND TARGACEPT FORM GLOBAL COLLABORATION AND LICENCE AGREEMENT FOR LATE-STAGE INVESTIGATIONAL PRODUCT TC-5214 FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER

AstraZeneca and Targacept, Inc. today announced a collaboration and licence agreement for the global development and commercialisation of TC-5214, Targacept's late-stage investigational product for major depressive disorder (MDD). TC-5214, which recently completed a phase IIb clinical trial, is a nicotinic channel blocker that is thought to treat depression by modulating the activity of various neuronal nicotinic receptor (NNR) subtypes.

Major Depressive Disorder is a common illness, affecting approximately 42 million people worldwide, and the global antidepressant market is valued at over \$20 billion. Serotonin re-uptake inhibitors (SSRIs) are the most commonly prescribed class of drugs for depression, but many patients fail to respond adequately. The NIMH STAR\*D study suggests that approximately 63 per cent of patients do not achieve remission with first-line SSRI treatment.

Under the agreement, AstraZeneca will make an upfront payment to Targacept of \$200 million upon effectiveness and up to an additional \$540 million if specified development, regulatory and first commercial sale milestones are achieved. Targacept will also be eligible to receive up to \$500 million if specified sales related milestones are achieved as well as significant stepped double-digit royalties on net sales worldwide. Targacept has retained an option for a co-promotion of TC-5214 to a limited target physician audience in the US. Effectiveness of the agreement is contingent on expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

AstraZeneca and Targacept will jointly design a global phase III clinical programme anticipated to begin in mid 2010 with the goal of filing a new drug application (NDA) with the US Food and Drug Administration (FDA) in 2012. TC-5214 is being developed as an adjunct to antidepressant therapy in adults with MDD who do not respond adequately to first-line antidepressant treatment. The companies will also initiate a phase II study exploring TC-5214 as a monotherapy for MDD. AstraZeneca will be responsible for 80 per cent of the cost of the initial global development programme, with Targacept responsible for the remaining 20 per cent. AstraZeneca will be responsible for and will fund the costs of global commercialisation of TC-5214, and will assume Targacept's manufacturing and supply agreements with third parties in relation to TC-5214. The agreement also provides for a specified period for the parties to negotiate a potential multi-year research programme that would be conducted by Targacept to identify and develop additional NNR Therapeutics for MDD and possibly other indications.

David Brennan, Chief Executive Officer of AstraZeneca said: "The opportunity to improve treatment in depression is a large one, both commercially and in terms of benefits for patients. It's an area both AstraZeneca and Targacept know well and I'm pleased to be adding another late stage project to our pipeline."

J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept, said: "We are delighted to have selected AstraZeneca to work with us to meet our goal of

advancing TC-5214 into late-stage development and bringing a new mechanistic approach for the treatment of depression to the millions of patients who do not respond well to first-line antidepressant therapy and need relief. Targacept and AstraZeneca have an established track record of successful collaboration and today's agreement demonstrates our shared dedication to excellence in the field of neuroscience.”

Targacept and AstraZeneca previously entered into a global collaboration focused on cognitive disorders in 2005. Three product candidates in the collaboration are currently in clinical development; including AZD3480 for attention deficit/hyperactivity disorder (ADHD), AZD1446 planned for Alzheimer's disease, and TC-5619, for cognitive dysfunction in schizophrenia.

#### About TC-5214

Scientific evidence suggests that depressive symptoms are associated with an overstimulation of NNRs and other receptors in the brain that are activated by the neurotransmitter acetylcholine. This overstimulation is referred to as increased cholinergic tone. TC-5214 has properties that modulate forms of NNR subtypes thought to be involved in the increased cholinergic tone associated with depression. In particular, TC-5214 blocks certain NNR channels. TC-5214 is the subject of issued patents that expire in the US and all major EU markets in 2020 and 2019, respectively. Additional patent term may be available via applicable patent term restoration laws. Targacept would be required to pay a percentage of amounts received from AstraZeneca under the agreement with respect to TC-5214 to the University of South Florida Research Foundation under the terms of an existing license agreement.

#### About TC-5214 Phase IIb data

The recently completed Phase II trial for TC-5214 in subjects who did not respond adequately to first-line treatment with the SSRI citalopram alone showed the primary outcome measure [mean change between treatment (TC-5214 + citalopram) and placebo (placebo + citalopram) from baseline on the HAM-D\*] and all secondary measures were statistically significant in favour of TC-5214 on an intent to treat basis. During this phase II trial, the most frequent adverse events were headache, dizziness and constipation. There was no clinically significant difference between the dose groups in discontinuations due to adverse events.

#### About Targacept

Targacept is a clinical-stage biopharmaceutical company that discovers and develops NNR Therapeutics™, a new class of drugs for the treatment of central nervous system diseases and disorders, in support of its vision of building health and restoring independence for patients. Targacept has clinical-stage product candidates in development for major depressive disorder, attention deficit/hyperactivity disorder, Alzheimer's disease and cognitive dysfunction in schizophrenia, as well as multiple preclinical programs. In addition to its collaboration with AstraZeneca, Targacept has a strategic alliance with GlaxoSmithKline. Targacept's news releases are available on its website at [www.targacept.com](http://www.targacept.com).

NNR Therapeutics™ is a trademark of Targacept, Inc.

#### About AstraZeneca

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of meaningful prescription medicines and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US\$ 31.6 billion and is a leader

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in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious disease medicines. For more information about AstraZeneca, please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

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3 December 2009

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Item 3

US FDA APPROVES SEROQUEL XR FOR ADD-ON TREATMENT OF MAJOR DEPRESSIVE DISORDER

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved once-daily SEROQUEL XR (quetiapine fumarate) Extended Release Tablets as adjunctive (add-on) treatment to antidepressants in adults with Major Depressive Disorder (MDD). SEROQUEL XR is the only medication in its class approved by the FDA to treat both major depressive disorder as adjunctive therapy and acute depressive episodes associated with bipolar disorder as monotherapy.

MDD affects approximately 14.2 million American adults in a given year, and today it is often treated with antidepressants. Selective serotonin reuptake inhibitors, or SSRIs, are among the most commonly prescribed class of antidepressant medications for depression; however, in many cases patients fail to respond adequately to treatment. Results from a National Institute of Mental Health study, STAR\*D, showed that approximately 63% of patients did not achieve remission with the SSRI citalopram when used as a first-line treatment. Additionally, this study reported that overall approximately one-third of patients with MDD failed to achieve study defined remission. This approval for SEROQUEL XR provides physicians with a new adjunctive treatment option for patients with MDD who have an inadequate response to their current antidepressant.

In addition to the FDA approval for the adjunctive indication in MDD, AstraZeneca has received a Complete Response Letter (CRL) from the FDA asking for additional information for the sNDAs for SEROQUEL XR as acute monotherapy and maintenance monotherapy for the treatment of MDD in adult patients.

AstraZeneca is evaluating the contents of the CRL. AstraZeneca will continue discussions with the FDA and will provide a response to the agency in due course. The CRL does not change the current recommendations for the treatment of patients taking SEROQUEL XR for approved indications in schizophrenia and bipolar disorder.

The FDA has required that AstraZeneca implement a Risk Evaluation and Mitigation Strategy (REMS). The REMS for SEROQUEL XR requires a Medication Guide and periodic assessments that will include a survey of patients' understanding of the potential risks of SEROQUEL XR. The REMS applies to all approved indications.

SEROQUEL XR is part of a class of drugs called atypical antipsychotics and is approved for a number of mental health disorders. In addition to today's approval for the adjunctive treatment of MDD, SEROQUEL XR is currently approved for the acute and maintenance treatment of bipolar disorder and schizophrenia.

Major Depressive Disorder sNDA Submission

The FDA approval of SEROQUEL XR for MDD was based on a supplemental new drug application (sNDA) comprising findings from two Phase III, placebo-controlled studies that assessed the efficacy and safety of once-daily treatment with SEROQUEL XR as adjunctive treatment in patients with MDD. Studies 6 and 7 were acute adjunctive therapy studies (with ongoing antidepressant therapy) involving 939 patients randomized (628 randomized to SEROQUEL XR) who had an inadequate response to their antidepressant therapy. Patients were on various antidepressants



prior to study entry including SSRIs (paroxetine, fluoxetine, sertraline, escitalopram, or citalopram), SNRIs (duloxetine and venlafaxine), TCA (amitryptiline) and other (bupropion).

The primary endpoint in these studies was the change from baseline to end of treatment in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score. The recommended dose range of SEROQUEL XR in MDD is 150 to 300mg/day.

In both studies efficacy with SEROQUEL XR was superior to placebo, as assessed by the primary endpoints. SEROQUEL XR 300 mg once daily as adjunctive treatment to other antidepressant therapy was superior to antidepressant alone in reduction of MADRS total score in both trials. SEROQUEL XR 150 mg once daily as adjunctive treatment was superior to antidepressant therapy alone in reduction of MADRS total score in one trial. In these studies, the most commonly observed adverse reactions associated with the use of SEROQUEL XR (incidence of 5% or greater and at least twice that of placebo) were somnolence (150 mg: 37%, 300 mg: 43%), dry mouth (150 mg: 27%, 300 mg 40%), fatigue (150 mg: 14%, 300 mg: 11%) and constipation (150 mg only: 11%). In addition, the adverse events seen with SEROQUEL XR in these studies were generally consistent with the known profile of SEROQUEL XR in other indications.

#### About AstraZeneca

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4 December 2009

- ENDS -

Item 4



<p>1. Identity of the issuer or the underlying issuer of existing shares to which voting rights are attached: ii</p>	<p>AstraZeneca PLC</p>
<p>2 Reason for the notification (please tick the appropriate box or boxes):</p>	
<p>An acquisition or disposal of voting rights</p>	<p><input checked="" type="checkbox"/></p>
<p>An acquisition or disposal of qualifying financial instruments which may result in the acquisition of shares already issued to which voting rights are attached</p>	<p><input type="checkbox"/></p>
<p>An acquisition or disposal of instruments with similar economic effect to qualifying financial instruments</p>	<p><input type="checkbox"/></p>
<p>An event changing the breakdown of voting rights</p>	<p><input type="checkbox"/></p>
<p>Other (please specify):</p>	<p><input type="checkbox"/></p>
<p>3. Full name of person(s) subject to the notification obligation: iii</p>	<p>BlackRock, Inc.</p>
<p>4. Full name of shareholder(s) (if different from 3.):iv</p>	<p>N/A</p>
<p>5. Date of the transaction and date on which the threshold is crossed or reached: v</p>	<p>1st December 2009</p>
<p>6. Date on which issuer notified:</p>	<p>4th December 2009</p>
<p>7. Threshold(s) that is/are crossed or reached: vi, vii</p>	<p>Holding has gone above 5%</p>



## 8. Notified details:

## A: Voting rights attached to shares viii, ix

Class/type of shares	Situation previous to the triggering transaction		Resulting situation after the triggering transaction				
	Number of Shares	Number of Voting Rights	Number of shares	Number of voting rights		% of voting rights x	
if possible using the ISIN CODE			Direct	Direct xi	Indirect xii	Direct	Indirect
GB0009895292	N/A	N/A	N/A	N/A	98,556,795	N/A	6.80%

## B: Qualifying Financial Instruments

## Resulting situation after the triggering transaction

Type of financial instrument	Expiration date xiii	Exercise/ Conversion Period xiv	Number of voting rights that may be acquired if the instrument is exercised/ converted.	% of voting rights

## C: Financial Instruments with similar economic effect to Qualifying Financial Instruments xv, xvi

## Resulting situation after the triggering transaction

Type of financial instrument	Exercise price	Expiration date xvii	Exercise/ Conversion period xviii	Number of voting rights instrument refers to	% of voting rights xix, xx	
					Nominal	Delta
CFD	N/A	N/A	N/A	2,328,386	0.16%	

## Total (A+B+C)

Number of voting rights	Percentage of voting rights
100,885,181	6.96%

9. Chain of controlled undertakings through which the voting rights and/or the financial instruments are effectively held, if applicable: xxi

On 1 December 2009, the Barclays Global Investors (BGI) business was acquired by BlackRock, Inc. The combined holdings of BlackRock, Inc following this acquisition triggered this disclosure requirement.

BlackRock Investment Management (UK) Limited – 100,885,181 (6.96%)

Proxy Voting:

10. Name of the proxy holder:

11. Number of voting rights proxy holder will cease to hold:

12. Date on which proxy holder will cease to hold voting rights:

13. Additional information:

BlackRock Compliance Disclosures Team

14. Contact name:

Stuart Watchorn

15. Contact telephone number:

020 7743 5741; stuart.watchorn@blackrock.com

8 December 2009

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Item 5

ADVISORY COMMITTEE BRIEFING MATERIALS FOR CRESTOR sNDA AVAILABLE ON US FDA WEB SITE

The US Food and Drug Administration (FDA) today posted briefing materials in advance of 15 December 2009 Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) to discuss the supplemental New Drug Application (sNDA) filed by AstraZeneca. The briefing materials can be found on the FDA web site.

In July, AstraZeneca announced that it had filed an sNDA with the FDA which seeks to incorporate outcomes data from the JUPITER study into the CRESTOR (rosuvastatin calcium) Prescribing Information. As noted in the FDA briefing materials, the sNDA filed by AstraZeneca includes a proposed draft indication based on the JUPITER study as follows:

“For the prevention of cardiovascular disease in adult patients with an increased risk of cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease, CRESTOR is indicated to:

- reduce the risk of total mortality
- reduce the risk of cardiovascular death
  - reduce the risk of stroke
- reduce the risk of myocardial infarction
- reduce the risk of arterial revascularization
  - reduce the risk of unstable angina”

Although included in the FDA briefing materials, the Advisory Committee is not expected to vote on the indication proposed by AstraZeneca.

According to the FDA briefing materials, the FDA Advisory Committee will vote on whether there is sufficient evidence of a favourable benefit-to-risk profile for rosuvastatin for the primary prevention of CVD in middle and older aged low-to-moderate cardiovascular disease (CVD) risk individuals with levels of LDL-C <130 mg/dL and hsCRP  $\geq$  2 mg/L. The FDA Advisory Committee will also discuss three non-voting questions related to imbalances in gastrointestinal-related deaths and confusional state as well as the investigator-reported diabetes as observed in JUPITER.

AstraZeneca looks forward to presenting and discussing the data on 15 December and to continuing to work with the FDA to progress the sNDA towards the approval of an indication that supports the appropriate use of CRESTOR on the basis of this data.

In adults, CRESTOR is prescribed along with diet for lowering high cholesterol. CRESTOR is also prescribed along with diet to slow the progression of atherosclerosis (the build-up of plaque in arteries) as part of a treatment plan to lower cholesterol to goal. The approved US indications are not scheduled to be part of the discussion at the upcoming meeting.

About JUPITER:

Results from the primary analysis of JUPITER (Justification for the Use of statins in Prevention: an Intervention Trial Evaluating Rosuvastatin), originally presented in November 2008 at the American Heart Association's Annual Scientific Sessions and published by the New England Journal of Medicine, evaluated the impact of rosuvastatin 20mg on reducing CV events (combined risk of myocardial infarction, stroke, arterial revascularization, hospitalization for unstable angina, or death from CV causes).

JUPITER was a long-term, randomized, double-blind, placebo-controlled, large-scale study of 17,802 patients designed to determine if rosuvastatin 20mg decreases the risk of myocardial infarction, stroke and other cardiovascular events in patients with LDL-C < 130mg/dL but at increased cardiovascular risk as identified by age and elevated high-sensitivity C-reactive protein (hsCRP). The majority of patients had at least one other risk factor including hypertension, low HDL-C, family history of premature coronary heart disease (CHD) or smoking. hsCRP is a recognized marker of inflammation which is associated with an increased risk of atherosclerotic cardiovascular events.

JUPITER is a part of AstraZeneca's extensive GALAXY clinical trials programme, designed to address important unanswered questions in statin research. Currently, more than 65,000 patients have been recruited from 55 countries worldwide to participate in the GALAXY programme.

About AstraZeneca

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11 December 2009

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Item 6

FAVOURABLE VOTE FROM FDA ADVISORY COMMITTEE ON BENEFIT/RISK OF CRESTOR IN JUPITER STUDY

On 15 December 2009, the US Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) voted 12 yes, 4 no, and 1 abstention that AstraZeneca has established sufficient benefit to offset the observed risks to support the use of CRESTOR (rosuvastatin calcium) in individuals meeting the following criteria:

- Men  $\geq$  50 years, women  $\geq$  60 years;
- Fasting LDL  $<$  130mg/dL; hsCRP  $\geq$  2.0mg/L; triglycerides  $<$  500mg/dL;
- No prior history of cardiovascular or cerebrovascular events or coronary heart disease (CHD) risk equivalent as defined by NCEP ATP-III guidelines.

The review, based on results of the JUPITER (Justification for the Use of statins in Prevention: an Intervention Trial Evaluating Rosuvastatin) study, is part of the FDA's evaluation of the supplemental New Drug Application (sNDA) filed by AstraZeneca in April 2009 to update the CRESTOR Prescribing Information with information about the impact of CRESTOR on reducing the risk of cardiovascular events.

"AstraZeneca welcomes the Advisory Committee's positive vote," said Howard Hutchinson, M.D., Chief Medical Officer, AstraZeneca. "Today's discussions will help guide our ongoing dialogue with the FDA regarding our request for an indication that supports the use of CRESTOR for the prevention of cardiovascular disease in patients with an increased risk of experiencing cardiovascular events."

The FDA Advisory Committee also discussed four non-voting items related to a range of other observations in JUPITER, including adverse events and whether the JUPITER trial identified an appropriate new target patient population.

The FDA frequently convenes advisory committee meetings to obtain independent expert guidance and opinions on clinical matters. While the FDA is not required to follow this guidance, the agency usually takes the advice into consideration when rendering its final decisions on pending applications and other public health matters.

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16 December 2009

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Item 7

ASTRAZENECA TO ACQUIRE INFECTION RESEARCH COMPANY NOVEXEL AND EXPAND  
COLLABORATION WITH FOREST LABORATORIES

AstraZeneca announced today that it has entered into an agreement to acquire Novexel, a private infection research company in France, and will collaborate with Forest Laboratories on the future co-development and commercialization of two late-stage antibiotic development programmes; ceftazidime/NXL-104 (CAZ104) and ceftarolin e/NXL-104 (CEF104). These antibiotic combinations utilise Novexel's novel investigational beta-lactamase inhibitor NXL-104 to overcome antibiotic-resistance and treat the increasing number of infections resistant to existing therapies.

AstraZeneca has agreed to acquire 100 per cent of Novexel's shares for \$350 million in cash payable at completion and will pay up to an additional \$75 million to Novexel shareholders if specified development milestones are reached. AstraZeneca will also transfer to Novexel shareholders an amount equivalent to the cash balance of Novexel at closing, approximately \$80 million. Under a separate agreement, AstraZeneca and Forest have agreed that following completion of the acquisition, Forest will pay Novexel, then an AstraZeneca group company, a sum equal to half of the acquisition costs of Novexel and half of any such specified development milestone payments in return for rights to CAZ104 in North America and the buy down of payment obligations in relation to CEF104 to Novexel from previous existing license arrangements. Effectiveness of the agreement is contingent on expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

CAZ104 is a combination of NXL-104 and ceftazidime, a third generation cephalosporin to which resistance has emerged. The addition of NXL-104 to ceftazidime extends its coverage of resistant Gram-negative pathogens including bacteria producing extended spectrum beta-lactamases. CAZ104 will be developed in serious infections requiring intensive care unit stays such as intra-abdominal,

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urinary tract and hospital acquired pneumonia. It is expected to move into Phase III development in late 2010 and to be filed with regulators in the US and EU in 2012.

CEF104 is a combination of NXL-104 and ceftaroline, Forest's broad spectrum anti-MRSA cephalosporin which is currently in late stage development. The addition of NXL-104 is designed to enhance the Gram-negative activity of ceftaroline to include resistant Gram-negative pathogens. The combination will be developed in indications where a mixed Gram-negative and Gram-positive profile can be of use, such as skin and diabetic foot infections. It is expected to move into Phase II development in late 2010.

Development costs of the two combination treatments will be shared between AstraZeneca and Forest. Forest will have rights to commercialise the antibiotic combinations in North America while AstraZeneca will have rights to commercialise these products in the rest of the world with the exception of CEF104 in Japan, where Takeda retains the rights for ceftaroline. AstraZeneca also will pay undisclosed royalties to Forest on AstraZeneca's international sales of the NXL-104 and ceftaroline combination. In addition to NXL-104 and its combinations, the Novoxel pipeline includes a Phase II oral anti-MRSA compound and several early stage and preclinical compounds.

Forest signed an agreement with Novoxel in January 2008 granting Forest rights to develop CEF104 in North America. AstraZeneca entered into an agreement with Forest in August 2009 to secure the rights to commercialise ceftaroline outside North America and Japan.

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“Building AstraZeneca’s anti-infective portfolio has become a strategic priority as antibiotic-resistant bacteria poses a growing threat to human health,” said Anders Ekblom, AstraZeneca Executive Vice-President of Development. “The innovative structure of this agreement allows us to build on our existing collaboration with Forest to create value, share costs, and reduce exposure to risk while developing two novel antibiotic combinations that address a growing problem for clinicians and patients. Utilising Novoxel’s NXL-104, these combinations have the potential to outwit bacteria that would otherwise be resistant to antibiotics.”

#### Antibiotic Resistance and Beta-Lactamase

As a class, beta-lactam antibiotics such as cephalosporins, penicillins and carbapenems have been very successful in treating bacterial infections. However, bacteria develop resistance to beta-lactams by producing a beta-lactam-destroying enzyme known as beta-lactamase. The effectiveness of beta-lactam antibiotics has been successfully restored and extended by using beta-lactamase inhibitors (BLI) which prevent this enzyme from destroying the antibiotic. Unfortunately in recent years new beta-lactamases have emerged with increased levels of resistance. Very few compounds are known to inhibit the significant range of over 500 currently known beta-lactamases, creating an opportunity for combinations with novel beta-lactamase inhibitors, such as NXL-104, to treat serious resistant infections. NXL-104 is a novel injectable beta-lactamase inhibitor believed to have the broadest spectrum coverage of the latest generation of beta-lactamase inhibitors.

#### Gram-positive and Gram-negative infections

Gram-positive bacteria, of which MRSA is just one example, are often the primary pathogens in skin, sinus, ear, and outpatient lung infections. Patients with these infections are generally managed on wards. Gram-negative bacteria, another category including for example E. coli & Pseudomonas, are often the primary pathogens in urine, gut and inpatient lung infections. These patients are sicker and often progress to be managed in intensive care units.

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Gram-positive infections have been the focus of infection research for a number of years, resulting in a choice of MRSA treatment options becoming available. However, with the recent rapid growth in resistance of Gram-negative pathogens to commonly used antibiotics, this area is now emerging as a major medical unmet need in both the established and emerging markets. Gram-negative pathogens are particularly problematic in the hospital setting, where they are increasing in prevalence and resistance and can cause severe life-threatening infections. Across the industry, the pipeline for new Gram-negative antibiotics is relatively empty compared with that of Gram-positive agents.

NOTES TO EDITORS:

About AstraZeneca

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of meaningful prescription medicines and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US\$ 31.6 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious disease medicines. For more information about AstraZeneca, please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

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Item 8

MEDIMMUNE REPLIES TO FDA COMPLETE RESPONSE LETTER ON MOTAVIZUMAB

AstraZeneca today announced that MedImmune, its biologics unit, has filed its formal regulatory reply to a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA). MedImmune received the CRL asking for additional information regarding motavizumab on 25 November 2008, and the company has been in ongoing discussions with FDA reviewers since then to complete and file its CRL reply.

The CRL is in connection with the Biologics License Application (BLA) for motavizumab for the prevention of serious respiratory syncytial virus (RSV) disease in high-risk infants, which was submitted on 30 January 2008. Motavizumab is an investigational monoclonal antibody (MAb) with enhanced activity against RSV compared to Synagis (palivizumab).

MedImmune was not required to conduct additional clinical trials in responding to the CRL. MedImmune will continue discussions with the FDA reviewers as needed throughout the remainder of the registration process.

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About MedImmune

MedImmune, the worldwide biologics business for AstraZeneca PLC (LSE: AZN.L, NYSE: AZN), has approximately 3,300 employees worldwide and is headquartered in Gaithersburg, Maryland. For more information, visit MedImmune's website at [www.medimmune.com](http://www.medimmune.com).

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