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AstraZeneca and Rigel Pharmaceuticals Sign Worldwide License Agreement for Late-Stage Development Product -- Fostamatinib Disodium (R788) -- for the Treatment of Rheumatoid Arthritis (RA)

SOUTH SAN FRANCISCO, Calif., Feb. 16 /PRNewswire-FirstCall/ -- AstraZeneca and Rigel Pharmaceuticals (Nasdaq: RIGL) today announced an exclusive worldwide license agreement for the global development and commercialization of fostamatinib disodium (R788), Rigel's late-stage investigational product for rheumatoid arthritis (RA) and additional indications. Fostamatinib disodium, which has completed a comprehensive phase 2 program, is the furthest developed oral Spleen Tyrosine Kinase (Syk) inhibitor being evaluated for RA. Inhibiting Syk is thought to block the intracellular signaling of various immune cells implicated in the destruction of bone and cartilage which is characteristic of RA.

RA is a systemic autoimmune inflammatory disease, which causes damage to the joints and other organs, affecting approximately 1 in 100 people. It is a major cause of disability and it is also associated with reduced life expectancy, especially if not adequately treated. Despite current treatment options, many patients still experience pain, worsening of joint destruction and disability, so new treatment options are needed. The RA market was estimated to be approximately $13bn globally in 2009, having grown from $1.3bn in 1998.

Once the agreement is effective, AstraZeneca will make an upfront payment to Rigel of $100 million with up to an additional $345 million payable if specified development, regulatory and first commercial sale milestones are achieved. Rigel will also be eligible to receive up to an additional $800 million of specified sales related milestone payments if the product achieves considerable levels of commercial success, as well as significant stepped double-digit royalties on net sales worldwide. AstraZeneca is responsible for all development, regulatory filings, manufacturing and global commercialization activities in all licensed indications under the contract. Effectiveness of the agreement is contingent on expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

AstraZeneca will design a global phase 3 program, anticipated to begin in the second half of 2010, with the goal of filing new drug applications with the US Food and Drug Administration

(FDA) and the European Medicines Agency (EMEA) in 2013. Fostamatinib disodium is being developed as a next generation oral RA therapy in adults who have failed to respond adequately to a traditional disease modifying anti-rheumatic drug (DMARD), such as methotrexate, where a TNF biologic add-on treatment would currently be considered. Under the terms of the agreement, AstraZeneca will also receive exclusive rights to Rigel's portfolio of oral Syk inhibitors, as well as for additional indications for fostamatinib disodium beyond RA.

Anders Ekblom, Executive Vice President of Development, of AstraZeneca said:

"There is a very real and pressing unmet medical need in the area of rheumatoid arthritis. Given the debilitating effect this disease can have on patients, AstraZeneca looks forward to working together with Rigel to continue development of this innovative investigational compound. Collaborations such as this one, which further strengthen our late-stage pipeline, demonstrate the key role externalization continues to play in AstraZeneca's strategy."

James M. Gower, chairman and chief executive officer of Rigel Pharmaceuticals, Inc. said: "This collaboration fulfills our expectations in two key ways. First, AstraZeneca has made an expansive commitment to develop fostamatinib disodium for the treatment of RA, which means that the work we have begun for patients with this disease will be completed with a substantially larger clinical program. Second, Rigel will receive royalties on potential future sales, appropriate to its investment in the development of R788."

NOTES TO EDITORS:

About Fostamatinib disodium

Fostamatinib disodium, which has completed a comprehensive phase 2 program is at the most advanced stage of development of the oral Spleen Tyrosine Kinase (Syk) inhibitors being evaluated for an RA indication. Inhibiting Syk is thought to block the intracellular signaling of various immune cells implicated in the destruction of bone and cartilage, which is characteristic of RA. Inhibition of Syk signaling is therefore a very attractive research approach to RA treatment.

About Fostamatinib disodium Phase 2 data

Three Phase 2 trials have been completed. TASKi1 and TASKi2 studied patients with an incomplete response to methotrexate. TASKi3 studied patients who had failed treatment with biologic therapies.

TASKi2 was a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of 457 RA patients in the target population of those with inadequate response to methotrexate. Treatment with stable doses of methotrexate in combination with fostamatinib disodium 100 mg twice daily, 150 mg once daily, or placebo were evaluated at six months. At six months, 100 mg twice daily fostamatinib disodium therapy (a dose planned to be taken forward in Phase 3) yielded responder rates of 66% versus 35% of the placebo group for the primary end point of ACR 20 improvement. ACR 50 response was achieved by 43% versus 19%: ACR 70 responder rates were observed in 28% versus 10%. All achieved p values of <0.001. DAS28 remission was achieved in 31% versus 7% ($p<0.01$).

This replicates the signal seen in the original smaller TASKi1 study in a similar population (n=189) where 100 mg of fostamatinib disodium twice daily yielded responses of 65% versus 38% of the placebo group for ACR20. ACR 50 response was achieved by 49% vs 19% and ACR70 was achieved by 33% vs 4%. DAS28 remission was achieved in 26% vs 8%. All of these endpoints achieved p values of $p < 0.05$ or better. In both studies clinical effect was seen as early as 1 week.

TASKi3 was a smaller study which included 219 patients who had failed biologic therapies. Although there was some evidence of efficacy on the MRI imaging, and on some other parameters, the study did not meet its primary endpoint.

These data indicate further studies of fostamatinib disodium are warranted in RA.

Combining all three trials, the most common side effects have been GI disturbances such as diarrhea, elevated blood pressure, transient and mild neutropenia, increased transaminases and a slight increase in infections, although not serious or opportunistic infections.

About Rigel Pharmaceuticals--(www.rigel.com)

Rigel is a clinical-stage drug development company that discovers and develops novel, small molecule drugs for the treatment of inflammatory/autoimmune diseases and metabolic diseases. Rigel's pioneering research focuses on intracellular signaling pathways and related targets that are critical to disease mechanisms. Rigel's productivity has resulted in strategic collaborations with large pharmaceutical partners to develop and market our product candidates. Rigel has product development programs in inflammatory/autoimmune diseases such as rheumatoid arthritis, thrombocytopenia and asthma, as well as in cancer.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US $32.8 billion in 2009. For more information please visit: www.astrazeneca.com

Rigel Forward-Looking Statements

This press release contains "forward-looking" statements, including, without limitation, statements related to the anticipated effectiveness of the agreement described in this press release and Rigel's receipt of an upfront cash payment from AstraZeneca, Rigel's potential receipt of development, regulatory and sales milestones and royalties on net sales worldwide, the potential market for and commercial potential of R788 and plans to pursue further clinical development of R788, including the timing thereof. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "estimate," "anticipate" and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based upon Rigel's current expectations and involve risks and uncertainties. There are a number of important factors that could cause Rigel's results to differ materially from those indicated by these forward-looking statements, including, without limitation, risks associated with entering into a corporate partnership agreement and reliance on a corporate partner,

including risks that if conflicts arise between us and our corporate partners, the other party may act in its self-interest and not in the interest of our stockholders and if any of our corporate partners were to breach or terminate its agreement with us or otherwise fail to conduct the partnership activities successfully and in a timely manner, the clinical development or commercialization of the affected product candidates or research programs could be delayed or terminated, as well as other risks associated with the timing and success of clinical trials and the commercialization of product candidates, potential problems that may arise in the clinical testing and approval process, market competition and other risks detailed from time to time in Rigel's SEC reports, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2009. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

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