





# GSK Exercises Option to Progress Development of ChemoCentryx's Traficet-EN for the Treatment of Inflammatory Bowel Diseases

LONDON and MOUNTAIN VIEW, Calif., Jan. 11 /PRNewswire/ -- GlaxoSmithKline (GSK) and ChemoCentryx, Inc. today announced that GSK has exercised its option to obtain an exclusive license for further development and worldwide commercialization of Traficet-EN™ (CCX282-B), a specific CCR9 antagonist with the potential to offer a new approach for the treatment of inflammatory bowel diseases, including Crohn's disease. The option also encompasses two further identified backup compounds and represents the first product licensing opportunity resulting from the original collaboration with ChemoCentryx through GSK's Centre of Excellence for External Drug Discovery (CEEDD).

Under the terms of the collaboration, ChemoCentryx will receive an option exercise fee of \$35 million and may be eligible for further regulatory milestone payments. Following successful development and commercialization of any of the candidate compounds, ChemoCentryx will also receive double-digit royalties on product sales with the ability to increase royalties by co-funding development through Phase III clinical trials and co-promoting to physician specialists in North America. GSK will now assume responsibility for the continued development of CCX282-B in patients with moderate-to-severe Crohn's disease. Potential ulcerative colitis studies will also be considered for this product candidate.

"Progressing the development of CCX282-B takes us closer to a valuable new treatment option for patients who suffer from these chronic, debilitating bowel diseases," said Moncef Slaoui, Chairman Research and Development, GSK. "CCX282-B may offer advantages over existing therapeutic approaches for Crohn's disease by potentially offering reduced side effects and convenient oral dosing to patients. This milestone also demonstrates the value of GSK's strategy of seeking early phase strategic collaborations with organizations conducting leading edge drug discovery, as it allows us to advance novel and innovative scientific research while sharing the risk involved in pursuing R&D into such areas."

ChemoCentryx recently completed and reported results from the placebo controlled phase II PROTECT-1 study (the Prospective Randomized Oral Therapy Evaluation in Crohn's disease Trial) with CCX282-B which demonstrated evidence of significant clinical efficacy in the reduction of disease severity in induction therapy, while results from the maintenance arm demonstrated clinical efficacy in maintenance of remission in patients with moderate-to-severe Crohn's disease. CCX282-B was shown to be well-tolerated after use up to one year.

"GSK's option exercise of CCX282-B is validation of ChemoCentryx's discovery and development capabilities and confirms the promise of our chemokine targeted development programs, many of which involve entirely new mechanisms of therapeutic action that have never been successfully regulated before," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "We are especially pleased with the progress and results of the PROTECT-1 study as it represents the first definitive clinical evidence that chemokine receptors can be successfully targeted to treat a major inflammatory disease such as Crohn's. Working with a partner of GSK's caliber has been inspiring and we look forward to the further advancement of CCX282-B as well as the additional programs that comprise our alliance."

The alliance provides GSK with access to certain drug candidates and their associated back-ups against pre-defined targets, with licensing options following successful completion of clinical proof-of-concept.

# About CCX282-B

CCX282-B is a small molecule, orally bioavailable drug that is administered in capsule form and which is believed to modify the inappropriate immune system response underlying inflammatory bowel disease (IBD) by blocking the CCR9 chemokine receptor. In adults, CCR9 is a highly specific receptor expressed by inflammatory T cells that migrate to the digestive tract. The trafficking of inflammatory cells to the small and large intestine is believed to cause the persistent inflammation seen in Crohn's disease and ulcerative colitis -- the two principal forms of IBDs. In addition to the recently completed PROTECT-1 study, ChemoCentryx has completed six Phase I clinical trials and one four-week Phase II Crohn's disease trial of CCX282-B at doses up to 1000 mg twice daily, demonstrating that the product candidate is well-tolerated and appropriate for once-daily or twice-daily oral dosing. CCX282-B may offer advantages over existing therapeutic approaches for Crohn's disease by potentially offering reduced side effects and convenient oral dosing to patients.

### **About Crohn's Disease**

Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract. It is estimated that the disease affects over 500,000 patients in Europe and North America. Patients suffer periods of flareups characterized by intense symptoms, interspersed with periods of relative remission where symptoms decrease or disappear. As Crohn's disease is a chronic condition, patients continue on therapy from the time of diagnosis over the course of a lifetime, layering additional therapies as flareups recur or persist in an effort to reduce symptoms. When medications can no longer control symptoms, patients have few options beyond surgery.

#### About GlaxoSmithKline

One of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit <a href="https://www.gsk.com">www.gsk.com</a>

### About ChemoCentryx

ChemoCentryx, Inc., is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing orally-administered therapeutics that target the chemokine and chemoattractant systems in order to treat autoimmune diseases, inflammatory disorders and cancer. The chemokine system is a network of secreted chemokine molecules, or ligands, and cell surface receptors that regulates inflammation. Based on its proprietary drug discovery and drug development platform, ChemoCentryx has internally generated multiple clinical and preclinical-stage programs, each targeting distinct chemokine and chemoattractant receptors with different small molecule compounds. ChemoCentryx's lead compound, Traficet-EN, a specific CCR9 antagonist, completed a Phase II/III multi-national clinical trial, called PROTECT-1, in patients with moderate-to-severe Crohn's disease. CCX025, also a CCR9 antagonist, successfully concluded a Phase I clinical program. Additional clinical programs include CCX140, which targets the CCR2 receptor, expected to enter Phase II clinical development in the first quarter of 2010 for the treatment of type 2 diabetes mellitus, and CCX354, a CCR1 antagonist in a Phase II clinical trial for the treatment of rheumatoid arthritis. ChemoCentryx also has several programs in preclinical development. ChemoCentryx is privately held. For more information, please refer to <a href="https://www.chemocentryx.com">www.chemocentryx.com</a>.

### Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2008.

# ChemoCentryx forward-looking statement

Any statements in this press release about ChemoCentryx's expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as may, believe, will, expect, anticipate, estimate, intend, predict, seek, potential, continue,

plan, should, could and would or the negative of these terms or other comparable terminology. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to (i) the initiation, timing, progress and results of ChemoCentryx's preclinical studies and clinical trials, (ii) ChemoCentryx's ability to advance product candidates into clinical trials, (iii) GSK's exercise of its license options, (iv) the commercialization of ChemoCentryx's product candidates, (v) the implementation of ChemoCentryx's business model, strategic plans for its business, product candidates and technology, (vi) ChemoCentryx's ability to maintain and establish collaborations or obtain additional government grant funding, (vii) ChemoCentryx's estimates of its expenses, future revenues, capital requirements and its needs for additional financing, (viii) the timing or likelihood of regulatory filings and approvals, (ix) the availability of corporate partners, (x) the scope of protection ChemoCentryx is able to establish and maintain for intellectual property rights covering its product candidates and technology, (xi) the impact of competitive products and technological changes, (xii) the availability of capital and the cost of capital, (xiii) ChemoCentryx's financial performance, (xiv) developments relating to ChemoCentryx's competitors and other vagaries in the biotechnology industry and (xv) other risks.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and ChemoCentryx undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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