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**For Immediate Release**

**SANTARUS SUBMITS IND FOR PHASE III CLINICAL TESTING  
OF RIFAMYCIN SV MMX IN TRAVELERS' DIARRHEA**

**SAN DIEGO (December 30, 2009)** – Santarus, Inc. (NASDAQ: SNTS), a specialty biopharmaceutical company, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) requesting approval to begin a Phase III clinical program evaluating rifamycin SV MMX<sup>®</sup> in patients with travelers' diarrhea.

In the IND, Santarus proposed two international multicenter, randomized, double-blind studies, each with approximately 300 patients, to assess the efficacy and safety of rifamycin SV MMX 400 mg (2 x 200 mg) oral tablets taken twice daily (800 mg total daily dose) for three days versus placebo in the treatment of patients with travelers' diarrhea. The primary endpoint of the Phase III clinical studies will be the time to last unformed stool (TLUS) and the studies will seek to demonstrate the superiority of rifamycin SV MMX to placebo.

Santarus expects to begin the first Phase III study in the first half of 2010. Assuming timely and successful completion, Santarus plans to initiate a second Phase III clinical study in travelers' diarrhea in the first half of 2011.

Santarus has licensed exclusive rights to develop and commercialize rifamycin SV MMX in the U.S. from Cosmo Technologies Limited, a wholly owned subsidiary of Cosmo Pharmaceuticals SpA (SIX:COPN). Cosmo conducted the rifamycin SV MMX Phase II clinical program, which consisted of two studies in a total of 155 patients with infectious diarrhea in Mexico, Turkey and South Africa, under Clinical Trial Applications with regulatory authorities in those countries.

Based on a pre-IND meeting in early 2009, the FDA determined that rifamycin SV MMX is a new molecular entity (NME) in the U.S. and requested a full preclinical assessment prior to submitting an IND. These preclinical studies have recently been completed, allowing Santarus to proceed with the submission of the IND.

“The filing of the IND is an important milestone in the rifamycin SV MMX clinical program, and we look forward to moving forward with the development of rifamycin SV MMX for patients with travelers' diarrhea,” said Gerald T. Proehl, president and chief executive officer.

Rifamycin SV MMX is a broad spectrum, semi-synthetic antibiotic with negligible systemic absorption that also has targeted release characteristics when taken orally. The application of MMX technology to rifamycin SV allows the antibiotic to be delivered directly to the colon, optimizing drug levels in the

colon where the pathogens of travelers' diarrhea are predominant. In addition to the targeted drug delivery, the company believes the negligible absorption of rifamycin SV MMX will offer an opportunity for limited side effects.

Cosmo's European partner, Dr. Falk Pharma GmbH, is planning to initiate in the first half of 2010 a Phase III clinical study in patients with travelers' diarrhea for registration of rifamycin SV MMX in the European Union (EU). The Dr. Falk Phase III study will assess the efficacy (non-inferiority) and safety of rifamycin SV MMX 400 mg (2 x 200 mg) oral tablets taken twice daily (800 mg total daily dose) for three days versus ciprofloxacin 500 mg tablets twice daily (1,000 mg total daily dose) in the treatment of patients with travelers' diarrhea. Assuming successful completion of the Phase III clinical program, Santarus and Dr. Falk plan to share their clinical data for inclusion in each company's respective regulatory submissions.

### **Travelers' Diarrhea/Infections of the Colon**

Infections of the colon are caused by bacteria, viruses or parasites. A common infection of the colon is travelers' diarrhea, which is primarily caused by the ingestion of food or water contaminated by bacteria. According to the U.S. Centers for Disease Control and Prevention, each year between 20% and 50% of international travelers (or an estimated 10 million people) develop diarrhea, with approximately 80% of the cases caused by bacteria.

### **MMX Technology**

The MMX technology consists of a sequence of lipophilic and amphiphilic matrices dispersed within a hydrophilic matrix. MMX tablets are coated with gastro-resistant polymers that protect the active pharmaceutical ingredient (API) against degradation in the upper gastrointestinal tract and delay the release of the API until the tablet reaches the colon. The MMX technology as applied to rifamycin SV MMX is covered by an issued U.S. patent that expires in 2020, and an additional patent application is pending at the U.S. Patent and Trademark Office.

### **About Santarus**

Santarus, Inc. is a specialty biopharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by gastroenterologists and other physicians. The company's current commercial efforts are focused on ZEGERID<sup>®</sup> (omeprazole/sodium bicarbonate), which is indicated for the treatment of certain upper GI diseases and disorders, and on GLUMETZA<sup>®</sup> (metformin hydrochloride extended release tablets), which is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Santarus is also developing two late-stage lower GI product candidates, budesonide MMX<sup>®</sup> and rifamycin SV MMX<sup>®</sup>, for the U.S. market. Budesonide MMX is being investigated in two multicenter Phase III clinical studies for the induction of remission of mild or moderate active ulcerative colitis. Santarus expects to begin Phase III clinical testing of rifamycin SV MMX in patients with travelers' diarrhea in the first half of 2010. More information about Santarus is available on the company's Web site at [www.santarus.com](http://www.santarus.com).

*Santarus cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. These forward-looking statements include statements regarding the timing of the Phase III clinical studies for rifamycin SV MMX. The inclusion of forward-looking statements should not be regarded as a representation by Santarus that any of its plans or objectives will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Santarus' business, including, without limitation: the timing for and outcome of the FDA's review of the IND for rifamycin SV MMX; whether the rifamycin SV MMX*

*Phase III clinical program will be successful and initiated and completed in a timely manner; other difficulties or delays in development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, Santarus' products; and other risks detailed in Santarus' prior press releases as well as in public periodic filings with the Securities and Exchange Commission.*

*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 Santarus undertakes no obligation to revise or update this news 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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