

Enanta Pharmaceuticals and Shionogi & Co., Ltd. Sign Agreement for Development and Commercialization of the First-in-Class Bridged Bicyclic Ketolide Antibiotic EP-013420 in Japan and East Asian Countries

WATERTOWN, Mass., July 27 /PRNewswire/ -- Enanta Pharmaceuticals today announced that Enanta and Shionogi & Co., Ltd. (Osaka, Japan) have entered into an agreement to develop and commercialize EP-013420, Enanta's first-in-class Bridged Bicyclic Ketolide antibiotic for the treatment of community respiratory tract infections, in Japan and certain East Asian countries. Enanta will retain exclusive development and marketing rights to EP-013420 in the rest of the world, including North America and Europe. Enanta plans to report the initiation of Phase 1 clinical trials on EP-013420 later this summer.

Under the terms of the agreement, Enanta received an upfront cash payment and an equity investment. In addition, Enanta could receive pre-commercialization payments for the successful development of EP-013420 and its back-up compound. Enanta will also receive royalties on product sales by Shionogi. The financial terms, while not disclosed, are within a range commonly found in the industry for an early clinical stage program with blockbuster potential.

Jay Luly, Ph.D., President and CEO of Enanta said, "This regional partnership provides us with a superb pharmaceutical partner in Asia, recognizes the potential of EP-013420 as a breakthrough community respiratory antibiotic and allows Enanta to retain the development and marketing rights in the rest of the world."

"Antibiotic resistance in the community is a serious public health concern around the world, and it is important that we continue to develop promising new antibiotics, such as EP-013420, which is effective against such resistant strains," said Motozo Shiono, President of Shionogi. "Partnering with innovative biotechnology companies in the United States is an important strategy for Shionogi, and our alliance with Enanta is consistent with this goal."

"Shionogi is the premier antibiotic company in Japan and has a prolific history of commercializing antibiotics, including Flomox(TM)," said Yujiro Hata, Vice President, Business Development of Enanta. "This alliance advances our corporate strategy to ensure the successful development and commercialization of EP-013420 worldwide with the leaders in the antibiotic field."

About EP-013420

Enanta is developing EP-013420 for the treatment of community respiratory tract infections with potential indications for community acquired pneumonia, acute exacerbation of chronic bronchitis, acute sinusitis, tonsillitis/pharyngitis, and otitis media. EP-013420 is a first-in-class Bridged Bicyclic Ketolide antibiotic that is the result of Enanta's innovative medicinal chemistry approach to creating novel and proprietary chemical

structures. Preclinical studies have shown an excellent pharmacokinetic profile for EP-013420 and an improved activity profile relative to currently marketed macrolides and ketolides, including against many strains of resistant *S. pneumoniae*. This is the most commonly implicated bacteria in respiratory infections, responsible for 45% of the cases of community acquired pneumonia (CAP) and 34% of acute sinusitis. Nearly one-third of *S. pneumoniae* infections in the US are resistant to penicillin and 31% are resistant to the macrolide antibiotic erythromycin. *S. pneumoniae* resistance is more common in Asia, where 53% of *S. pneumoniae* infections are penicillin resistant and 80% are erythromycin resistant.

The global respiratory antibiotic market was approximately \$12 billion in 2002. Three major antibiotic classes dominate the respiratory antibiotic market: macrolides, beta-lactams, and quinolones. Of these classes, several respiratory antibiotics generate annual sales well in excess of \$1 billion. Worldwide sales of macrolide drugs amounted to approximately \$5.6 billion in 2003. Macrolides alone represented almost 20% percent of the total antibiotic sales in 2000 and are expected to retain this share over time.

About Shionogi

Shionogi & Co., Ltd. is one of Japan's largest research based pharmaceutical companies: developing, manufacturing, distributing, importing and exporting pharmaceuticals and diagnostics. Shionogi's fundamental company policy is to constantly strive to provide medicine of the best possible kind essential for the protection of the health of people worldwide. For additional company information, please visit Shionogi on the World Wide Web at <http://www.shionogi.co.jp>.

About Enanta

Enanta Pharmaceuticals is a research and development company, which uses its novel chemistry approach and drug discovery capabilities to create best in class small molecule drugs in the anti-infective field. At the heart of Enanta is its commitment to innovative chemistry that surpasses traditional medicinal chemistry approaches. The Company successfully integrates chemistry with biology, in order to discover and develop novel small molecules that address the following significant, unmet medical needs: a new class of macrolide and ketolide antibiotics to overcome bacterial resistance and antiviral agents targeted against the Hepatitis C virus (HCV). Enanta is a privately held company with offices in Watertown, MA. More information about the company can be found at <http://www.enanta.com>.

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