

## FOR IMMEDIATE RELEASE

### ADVANCEMENT OF ASCENDIA PHARMACEUTICAL'S NANO-EMULSION TECHNOLOGY PLATFORM WITH ITS LEAD DEVELOPMENT PROGRAM ASD-002

*A novel, injectable formulation of the thienopyridine-class anti-platelet drug clopidogrel*

NORTH BRUNSWICK, NJ — (BUSINESS WIRE) — September 04, 2014 — [Ascendia Pharmaceuticals](#), a start-up specialty pharmaceutical company in the business of providing formulation technologies and product development services for poorly soluble molecules, today announced that the company has successfully applied its nano-emulsion technology platform to a novel injectable formulation of clopidogrel - the world's top-selling blood thinner medicine. Ascendia has advanced the program to pre-IND development stage, and has filed US and worldwide PCT patent applications on the product.

“There is a significant unmet medical need for a parenteral clopidogrel dosage form for the treatment of Acute Coronary Syndrome under life-threatening situations,” said [Jingjun “Jim” Huang, Ph.D.](#), CEO of Ascendia. “With our nano-emulsion platform technology, Ascendia has demonstrated that a ready-to-use, stable and soluble, parenteral form of clopidogrel is both technically and commercially feasible - by addressing the solubility, physical and chemical stability, API sourcing, manufacturing, and delivery challenges of this difficult compound.” Ascendia was founded in 2012 by Dr. Huang and has its commercial operations in North Brunswick, NJ.

#### About ASD-002

ASD-002 is a parenteral form of clopidogrel formulated as an oil-in-water nano-emulsion suspension. Ascendia is developing ASD-002 for the treatment of Acute Coronary Syndrome - which refers to either unstable angina or when blood supply to the coronary arteries becomes suddenly fully or partially blocked (i.e., a myocardial infarction). When a patient presents with a suspected coronary event, a 300-600 mg loading dose of clopidogrel is frequently administered. However, the only commercially available dosage forms of clopidogrel are oral tablets in 300 mg and 75 mg strengths - not ideal for administration in an emergency setting. Also, when delivered orally there is a significant

delay in the time required for the medicine to become effective - although clopidogrel is rapidly absorbed, the time to reach peak concentration and therapeutic effect can require several hours. Therefore, in an acute, emergency setting, a more rapidly acting, injectable clopidogrel dosage form is desirable.

The barrier to developing such a product is due to clopidogrel's challenging solubility, physical form, and chemical stability properties. Clopidogrel is practically insoluble in water (the oral tablet composition uses the bisulfate salt form of clopidogrel which is soluble at gastric pH, but not suitable for injection). Clopidogrel free-base is a semi-solid, viscous, oily form, thus presenting difficulties in storage, dispensing and processing. Moreover, the free-base form is chemically unstable and undergoes both hydrolysis and oxidation. In addition, clopidogrel is a chiral molecule - only the S-enantiomer is biologically active, and chiral conversion to the R-enantiomer can easily occur in a liquid dosage form. ASD-002 overcomes these stability and delivery challenges by stabilizing the free-base form of clopidogrel in the nano-emulsion formulation.

#### About Ascendia Pharmaceuticals LLC

Ascendia is a specialty pharmaceutical company dedicated to developing enhanced formulations of existing drug products, and enabling formulations for pre-clinical and clinical stage drug candidates. We specialize in creating formulation solutions for poorly-water soluble molecules - using our suite of nano-particle technologies, we can assess the feasibility of a broad array of formulation options in order to improve a drug's bioavailability. We execute rapid, comprehensive, and cost-effective programs for our clients. We have three technology platforms - EmulSol for producing nano-emulsions, AmorSol for creating amorphous solid dispersions, and NanoSol for formulating nano-crystals. Ascendia provides development and testing services - from discovery-stage molecules to life-cycle-management projects - creating formulation solutions with enhanced biopharmaceutical properties suitable for clinical scale-up. For more information, please visit Ascendia's website at [www.ascendiapharma.com](http://www.ascendiapharma.com).

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