

Strongbridge Biopharma plc Announces Presentation of COR-003 and COR-005 Data at the European Congress of Endocrinology

May 31, 2016 7:31 AM ET

DUBLIN, Ireland and TREVOST, Pa., May 31, 2016 (GLOBE NEWSWIRE) -- Strongbridge Biopharma plc (Nasdaq:SBBP), a global rare disease biopharmaceutical company focused on the development and commercialization of novel therapeutic options, today announced that data from pre-clinical and Phase 1 clinical studies for COR-003 (levoketoconazole) and COR-005 (veldotide) were presented at the 18th European Congress of Endocrinology held in Munich, Germany from May 28-31, 2016.

“As a company passionately working to accelerate development of its rare endocrine disease franchise, we were pleased to participate in the exchange of exciting new research findings for the rare disease community at the European Congress of Endocrinology,” said Matthew Pauls, president and chief executive officer of Strongbridge Biopharma. “The pharmacology data presented support the rationale for our ongoing clinical studies of COR-003 in Cushing’s syndrome and COR-005 in acromegaly, which have the potential to be innovative new treatment options for these disease areas where there is considerable unmet need.”

COR-003, Strongbridge’s lead product candidate, is a cortisol synthesis inhibitor currently being studied in the global Phase 3 SONICS trial for the treatment of endogenous Cushing's syndrome. COR-005 is a next-generation somatostatin analog (SSA) with a unique receptor binding and activation profile to somatostatin receptor subtypes, being investigated for the treatment of acromegaly, with potential additional applications in Cushing's disease and neuroendocrine tumors.

“Treating rare diseases like Cushing’s syndrome and acromegaly are fraught with challenges and limitations. In fact, nearly 80 percent of acromegaly patients are not well controlled on existing first-line therapy alone and up to 20 percent may have not have a response at all,” said Klaus Kutz, M.D., professor of medicine at the University of Bonn in Germany, independent consultant in clinical pharmacology and safety, and principal investigator of the COR-005 Phase 1 studies. “These data provide important insights into how new investigational treatments such as COR-003 and COR-005 may help to restore the harmony of critical hormones in the bloodstream, all of which are tightly regulated by one another and direct vital body functions such as growth and development, reproduction, and metabolism.”

Poster Presentation Details:

- **Guided Poster #123 (Neuroendocrinology)** – [A placebo-controlled study to assess the dose-effect of COR-005, a novel somatostatin analogue on plasma glucose regulation compared to octreotide in healthy male subjects](#); *Klaus Kutz*; Sunday, May 29, 2016 – 13:15-14:15 GMT
- **Guided Poster #158 (Pituitary Clinical 1)** – [Differentiated pharmacokinetics of levoketoconazole \(COR-003\), the single 2S,4R-enantiomer of ketoconazole, a new investigational drug for the treatment of Cushing’s syndrome](#); *Ruth Thieroff-Ekerdt*; Monday, May 30, 2016 – 13:15-14:15 GMT
- **ePoster #699** – [A placebo-controlled study of repeated subcutaneous doses of COR-005 alone or with octreotide on GHRH-stimulated GH and pharmacokinetics in healthy male subjects](#); *Klaus Kutz*

About Strongbridge Biopharma

Strongbridge Biopharma is a global rare disease biopharmaceutical company focused on the development and commercialization of novel therapeutic options. Strongbridge’s lead product candidate, COR-003 (levoketoconazole), is a cortisol inhibitor currently being studied in the global Phase 3 SONICS trial for the treatment of endogenous Cushing's syndrome. Strongbridge’s rare endocrine disease franchise also includes COR-005, a next-generation somatostatin analog (SSA) being investigated for the treatment of acromegaly, with potential additional applications in Cushing's syndrome

and neuroendocrine tumors. Both COR-003 and COR-005 have received orphan designation from the U.S. Food and Drug Administration and the European Medicines Agency. For more information, visit www.strongbridgebio.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, are forward-looking statements. These statements relate to future events and involve known and unknown risks, including, without limitation, uncertainties regarding Strongbridge's strategy, plans, outcomes of product development efforts, costs and results, future financial position and objectives of management for future operations. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "potential," "project," "target," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations, estimates, forecasts and projections and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. The forward-looking statements contained in this press release are made as of the date of this press release, and Strongbridge Biopharma does not assume any obligation to update any forward-looking statements except as required by applicable law.

Contacts:

Corporate and Media Relations
Elixir Health Public Relations
Lindsay M. Rocco
+1 862-596-1304
lrocco@elixirhealthpr.com

Investor Relations
The Trout Group
Marcy Nanus
+1 646-378-2927
mnanus@troutgroup.com

USA
900 Northbrook Drive
Suite 200
Trevose, PA 19053
Tel. +1 610-254-9200
Fax. +1 215-355-7389



Strongbridge Biopharma plc