ATL1103: Data Presentation at the Society for Endocrinology BES 2015 Conference

Antisense Therapeutics Limited (“ANP” or the “Company”) wishes to advise that its licensing partner of ATL1103 (Strongbridge Biopharma) announced overnight in the US that results from a secondary efficacy analysis of the completed Phase 2 trial for COR-004 (ATL1103) in adult patients with acromegaly will be presented at the Society for Endocrinology BES 2015 conference being held in Edinburgh, UK from November 2-4, 2015.

For further details please refer to their Press Release which is attached.

Contact Information:
Website: www.antisense.com.au
Managing Director: Mark Diamond +61 (0)3 9827 8999

About Antisense Therapeutics Limited
Antisense Therapeutics Limited is an Australian publicly listed biopharmaceutical drug discovery and development company. Its mission is to create, develop and commercialise second generation antisense pharmaceuticals for large unmet markets. Antisense Therapeutics has 4 products in its development pipeline that it has in-licensed from Isis Pharmaceuticals Inc. (ISIS), a world leader in antisense drug development and commercialisation - ATL1102 (injection) which has successfully completed a Phase II efficacy and safety trial, significantly reducing the number of brain lesions in patients with relapsing-remitting multiple sclerosis (RRMS), ATL1103 drug designed to block GHr production which in a Phase II clinical trial, successfully reduced blood IGF-1 levels in patients with the growth disorder acromegaly, ATL1102 (inhaled) which is at the pre-clinical research stage as a potential treatment for asthma and ATL1101 a second-generation antisense drug at the pre-clinical stage being investigated as a potential treatment for cancer.

About ATL1103
ATL1103 is a second-generation antisense drug designed to block growth hormone receptor (GHr) expression thereby reducing levels of the hormone insulin-like growth factor-1 (IGF-1) in the blood and is a potential treatment for diseases associated with excessive growth hormone and IGF-1 action. These diseases include acromegaly, an abnormal growth disorder of organs, face, hands and feet, diabetic retinopathy, a common disease of the eye and a major cause of blindness, diabetic nephropathy, a common disease of the kidney and major cause of kidney failure, and some forms of cancer. Acromegalic patients have significantly higher blood IGF-1 levels than healthy individuals. Reduction of these levels to normal is accepted by clinical authorities as the primary marker of an effective drug treatment for the disease. GHr is a clinically validated target in the treatment of acromegaly. In the case of diabetic retinopathy, published clinical studies have shown that treatments producing a reduction in IGF-1 levels retarded the progression of the disease and improve vision in patients. Scientific papers have been published on the suppression of blood IGF-1 levels in mice (Tachas et al., 2006, J Endocrinol 189, 147-54) and inhibition of retinopathy in a mouse retinopathy model (Wilkinson-Berka et al., 2007, Molecular Vision 13, 1529-38) using an antisense drug to inhibit the production of GHr. In a Phase I study in healthy subjects, ATL1103 demonstrated a preliminary indication of drug activity, including suppression of IGF-1 and the target GHr (via circulating growth hormone binding protein) levels. In a Phase II trial in acromegalic patients, ATL1103 met its primary efficacy endpoint by showing a statistically significant average reduction in sIGF-1 levels from baseline (P<0.0001) at week 14 (one week past the last dose) at the twice weekly 200 mg dose tested. Antisense is currently undertaking a higher dose study (2 x 300 mg/week) in acromegaly patients. Under its technology collaboration with ISIS, Antisense Therapeutics’ will pay ISIS a percentage (single digit) of the licensing revenue it earns from ATL1103.
Strongbridge Biopharma plc Announces Data Presentation at the Society for Endocrinology BES 2015 Conference

Secondary Analysis from Phase 2 Study Supports Novel Mechanism of Action of COR-004 to Reduce IGF-1 in Patients with Acromegaly by Inhibiting Growth Hormone Receptor (GHR) Expression

November 3, 2015 – Dublin, Ireland and Trevose, Pa., – Strongbridge Biopharma plc (NASDAQ: SBBP) today announced that results from a secondary efficacy analysis of the completed Phase 2 trial for COR-004 in adult patients with acromegaly will be presented at the Society for Endocrinology BES 2015 conference being held in Edinburgh, UK from November 2-4, 2015.

The Phase 2 clinical trial was a randomized, open-label, parallel group clinical trial of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous administration regimens of COR-004 in 26 adult patients with acromegaly treated over 13 weeks. The trial met its key efficacy endpoint demonstrating a statistically significant average reduction in the serum insulin-like growth factor 1 (IGF-1) levels from baseline in the higher dose group. COR-004 was safe and well tolerated. The main adverse event was mild to moderate injection site reactions in the majority of patients.

As one of the secondary endpoints, the level of growth hormone (GH)-binding protein (GHBP) as a marker of growth hormone receptor (GHR) expression was evaluated. With the larger dose, a continuous decrease in GHBP was found that reached statistical significance at the end of the study, coinciding with a significant reduction in IGF-1. These data provide further evidence for the efficacy of COR-004 and its ability to inhibit growth hormone receptor (GHR) expression. Data from future clinical trials will help to evaluate the relationship between COR-004 dose, GH levels, GHBP levels and the change in IGF-1 with treatment.

The poster presentation information is listed below:

Presentation Title: In patients with acromegaly antisense oligomer therapy directed at the GH receptor is associated with reduction in circulating GHBP levels
Date: Tuesday, November 3, 2015
Time: 1:00 p.m. to 2:15 p.m. (GMT)
Session Title: Pituitary
Location: Lennox Suite Exhibition Hall
Abstract Number: P308

Earlier this year, Strongbridge Biopharma plc entered into an exclusive licensing agreement for commercialization rights to Antisense Therapeutics’ ATL1103, now known as COR-004, for endocrinology applications.
About Strongbridge Biopharma

Strongbridge Biopharma’s strategic focus is to build a biopharmaceutical company focused on the development, in-licensing, acquisition and eventual commercialization of complementary product candidates across multiple franchises that target rare diseases. Strongbridge Biopharma’s lead product candidate, COR-003 (levoketoconazole), is a cortisol inhibitor that is currently being studied in the global Phase 3 trial for the treatment of endogenous Cushing’s syndrome. COR-003 has received orphan designation from both the European Medicines Agency and the U.S. Food and Drug Administration. Strongbridge Biopharma recently expanded its rare endocrine disease franchise with the completion of transactions for two Phase 2 product candidates: COR-004, a novel second-generation antisense compound, which is in clinical development for acromegaly and designed to block the synthesis of growth hormone receptor (GHR) thereby reducing levels of insulin-like growth factor-1 (IGF-1) in the blood; and COR-005, a next-generation somatostatin analog (SSA) with a unique receptor affinity profile, being investigated for the treatment of acromegaly, with potential additional applications in Cushing’s disease and neuroendocrine tumors. Strongbridge Biopharma’s intent is to independently commercialize its rare endocrine assets in key global markets.

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, outcomes of product development efforts 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 Rocco
+1 862-596-1304
lrocco@elixirhealthpr.com

Investor Relations
ICR Inc.
Stephanie Carrington
+1 646-277-1282