

LONDON, November 12, 2013 /PRNewswire/ --

Shield Therapeutics, an independent specialty pharmaceutical company focused on the development of mineral-derived hospital pharmaceuticals, today announces that it has filed an investigational new drug (IND) application with the US Food and Drug Administration (FDA) to initiate a Phase 3 pivotal study of ST10, its novel oral iron-replacement therapy, for the treatment of iron deficiency anaemia (IDA) in pre-dialysis patients with chronic kidney disease (CKD).

ST10 is a novel oral ferric iron therapy being developed for the treatment of iron deficiency which has demonstrated potential as an effective oral alternative to parenteral (IV) iron in ferrous intolerant patients. Previous clinical studies have shown that gastrointestinal absorption of ST10 is at least as good as ferrous products, however ST10 has minimal gastro-intestinal side effects so can be given on an empty stomach and is therefore given at a significantly lower daily dose. As ST10 is not adversely affected by changes in gastric pH, it can also be co-prescribed with widely used acid-reducers.

The British National Formulary states: 'parenteral iron does not produce a faster response than oral iron provided the oral iron is taken reliably and is absorbed adequately.' ST10 aims to deliver this compelling alternative to prescribers, patients and payors, in addition to avoiding the inconvenience, high cost and life-threatening hypersensitivity risks associated with IV infusions.

The 16-week prospective, multicentre, randomised, double-blind, placebo controlled AEGIS 3 study will enrol pre-dialysis CKD patients in the USA who have a diagnosis with iron deficiency anaemia. ST10 is also currently being investigated in a pivotal Phase 3 study as a potential treatment for IDA in inflammatory bowel disease, top-line results from which are expected towards the end of 2013.

Epidemiology data suggests the current total IDA patient population in the EU, USA and Japan is approximately 34m, with an addressable population of 2.6m (IBD and CKD in the EU and US) in the first instance. The core market in IDA is worth at least

\$3.0bn

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\$11.6billion

by 2018

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Carl Sterritt, Founder and Chief Executive Officer of Shield Therapeutics, stated: "We are excited about the market potential of ST10 and the filing of this IND application marks another important milestone in the development of ST10 as we move into a second major indication. We believe the benefits ST10 will deliver to patients with CKD who cannot tolerate oral ferrous iron therapy, coupled with the convenient nature of its administration, will make ST10 a leader in the future treatment paradigm of IDA in CKD."

[¹]Chronic Kidney Disease (CKD) Therapeutics - Pipeline Assessment and Market Forecasts to 2018, GlobalData, September 2011

About Shield Therapeutics

Shield Therapeutics (<http://www.shieldtherapeutics.com>), founded in 2008, is an independent specialty pharmaceutical company focused on the development and commercialisation of late-stage, mineral-derived hospital pharmaceuticals which address areas of high unmet medical need. Shield is currently conducting pivotal Phase 3 studies of its lead asset, ST10, for the treatment of iron deficiency anaemia associated with inflammatory bowel disease and is soon to commence a Phase 3 study of ST10 for the treatment of iron deficiency anaemia in patients with chronic kidney disease.

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