Atlantic Healthcare receives FDA agreement to initiate rolling submission of its New Drug Application for alicaforsen in the treatment of pouchitis

FDA to accept sections of the regulatory application ahead of final Phase 3 data expected in the second half of 2017

Cambridge, UK, and Raleigh, NC; 24 January 2017. Atlantic Healthcare plc, an emerging trans-Atlantic pharmaceutical company with a core focus on gastrointestinal (GI) disorders, announces that it has received agreement from the U.S. Food and Drug Administration (FDA) to initiate a rolling submission of its New Drug Application (NDA) for alicaforsen to treat pouchitis, a serious form of inflammatory bowel disease (IBD) that has limited treatment options.

Toby Wilson Waterworth, CEO at Atlantic Healthcare, said: *"Following a meeting with the FDA in December 2016, in which we discussed the preclinical (safety) package for alicaforsen, we are delighted to announce that the FDA accepted our request for a rolling submission of the NDA for alicaforsen in pouchitis. We expect to complete the NDA submission, following successful completion of our ongoing pivotal Phase 3 trial of alicaforsen in pouchitis."*

The rolling submission follows previously granted FDA Fast-Track designation for alicaforsen in the treatment of pouchitis. Fast-Track designation is designed to facilitate the development, and when appropriate expedite the review, of medicines that are intended to treat serious conditions and address unmet medical needs. It allows more frequent communication with the FDA, the option for rolling submission, and potential eligibility for accelerated approval.

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Notes to Editors:

About Atlantic Healthcare plc (www.atlantichc.com)
Atlantic Healthcare (the Group) is an emerging trans-Atlantic pharmaceutical company with a core focus on gastrointestinal disorders including Inflammatory Bowel Disease (IBD). The Group's lead product is alicaforsen enema, in a pivotal Phase 3 trial for pouchitis, and in preparation for Phase 3 clinical development in ulcerative colitis (UC). Alicaforsen is also generating early repeat revenues in Europe through unsolicited requests via the Named Patient Supply protocols. The

Group has FDA and EMA orphan drug designations, and an FDA letter of Fast Track, in pouchitis. Atlantic Healthcare has a highly committed investor base, and an experienced international management team. Atlantic Healthcare's fundraising to date includes £1.9m through SBRI funding with InnovateUK, the UK Government's innovation agency (www.innovateuk.gov.uk). In 1Q 2016 the Group closed a $24m round led by LDC (the private equity division of Lloyd's Banking Group), with investment from founders of both Salix Pharmaceuticals and Clinigen Group, and existing shareholders.

About Alicaforsen

Alicaforsen is being developed as a locally active, topical formulation with the potential to establish a new class of therapy, with clear differentiating features, for the treatment of inflammatory bowel disease (IBD).

Alicaforsen enema is currently in a Phase 3 trial agreed with U.S., Canadian and European regulatory agencies in patients with active, chronic pouchitis. The trial is recruiting 138 patients to approximately 40 trial centres across the U.S., Canada, Europe, and Israel. Alicaforsen enema is in preparation to commence a pivotal Phase 3 for active distal ulcerative colitis (UC). There is currently no approved treatment for pouchitis in the U.S. or Europe and there are limited treatment options for UC.

Alicaforsen has shown in five Phase 2 clinical studies involving 377 patients to reduce inflammation and promote mucosal healing with good tolerability and a durable effect. Alicaforsen also has a good safety profile based on data from more than 1,000 patients.

Alicaforsen is an antisense oligonucleotide with a novel mode of action for treatment of IBD. Alicaforsen targets ICAM-1, a cell-surface protein that is involved in the inflammatory response and is over-expressed in patients with IBD. As noted above, alicaforsen in pouchitis has FDA Fast Track designation, plus U.S. and European orphan drug designations. Alicaforsen is generating early repeat revenues in Europe through unsolicited requests via the Named Patient Supply protocols. This has demonstrated further evidence of efficacy and safety in the pouchitis[1] and UC indications [2,3].

References:

1. Alicaforsen, an antisense inhibitor of ICAM-1, as treatment for chronic refractory pouchitis after proctocolectomy: A case series. Thomas Greuter, Luc Biedermann, Gerhard Rogler, Bernhard Sauter and Frank Seibold. UEG Journal (2015) DOI: 10.1177/2050640615593681
2. Alicaforsen Retention Enema Induces Long-Term Remission in Patients with Ulcerative Colitis. Zaid Heetun, David Gibson, Denise Keegan, Kathryn Byrne, Hugh E Mulcahy, Garret Cullen, Glen A Doherty. Irish Soc Gastroenterol Nov 2014
3. Alicaforsen, ICAM-1 enema as a treatment option when treating distal ulcerative colitis . LA. Bark 1 , I. Löfberg 1 , B. Håkansson 1 , U. Sjöqvist 1 (http://www.atlantichc.com/la-bark-abstract-pdf)

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