



Orphan Drug Status Granted to Vesimune for Bladder Cancer

Bioggio, Switzerland, 8 December 2014 - Telormedix, a clinical stage biopharmaceutical company focused on TLR7 agonists in the treatment of cancer and infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to Vesimune for the treatment of *carcinoma in situ* (CIS) in the bladder.

The FDA grants orphan drug status to products for rare diseases and defines a rare disease as one with a prevalence of less than 200,000 cases in the USA. As there are approximately 60.000 cases of non-muscle invasive CIS of the bladder, it is clearly a rare disease meaning that the orphan designation was extended to Vesimune.

Vesimune is Telormedix' lead product, a TLR-7 agonist, that has successfully completed a Phase II trial in CIS of the bladder. The product is a unique sterile liquid formulation of a marketed immune modulatory compound, designed on innovative technology principles to carrier drug delivery systems in order to increase solubility, bio-adhesiveness and stability. These properties mean that the product can be used in therapeutic settings that the original product could not.

Johanna Holldack, CEO of Telormedix, commented: "This is fantastic news that vindicates our development strategy. With Vesimune having completed Phase II and with this orphan drug designation, we are now in a pivotal position for discussions with potential license partners."

– Ends –

Notes for Editors

About Vesimune

Telormedix' lead product, Vesimune (TMX-101), is a proprietary targeted small molecule for the treatment of superficial bladder cancer. The active ingredient in Vesimune is a known immunomodulatory molecule with a favourable safety profile and a demonstrated clinical efficacy in oncological and viral diseases. The Company expects that this targeted therapy will have an improved safety and efficacy profile in comparison to standard of care. Telormedix has taken advantage of existing regulatory data and clinical experience in order to bring Vesimune quickly through Phase I/II clinical trials.

About Telormedix

Telormedix (www.telormedix.com), founded in October 2007, is a biopharmaceutical company focused on targeted immunity and modulation of the innate immune system for treating cancer and infectious diseases. The Company's lead product, Vesimune (TMX-101), has just successfully completed a Phase II clinical trial for the treatment of CIS (carcinoma in situ) of the bladder. In addition, Telormedix is developing two additional TLR7-targeted molecules, TMX-201 and TMX-202 both of which would make good vaccine adjuvants. As these molecules have substantially improved pharmacokinetics and pharmacodynamics profiles they have the potential to fully realise the anticancer promise of TLR 7 agonists. One of these molecules, TMX-202 has recently been selected for preclinical study for the topical treatment of skin cancers and other indications. The candidate has already successfully completed a number of in vivo studies.

Located in Switzerland, Telormedix is led by a highly experienced management team and backed by an international consortium of venture capitalists, Aravis (Zurich, Switzerland) and Proquest Investments (Florida, USA).

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