Creabilis Therapeutics Receives MHRA Authorization to Carry Out Phase I Clinical Trial in the UK for Topical CT327

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Press Release Summary = Colleretto Giacosa (Torino, Italy) May 30, 2007 – **CREABILIS therapeutics SpA** announced that it has received authorization from the **British Medicines and Healthcare products Regulatory Agency (MHRA)** to carry out a Phase I Clinical Trial for **CT327** in the UK.

Press Release Body = **CT327** is a new chemical entity obtained throughout the application of the **CREABILIS** proprietary technology called "**MiniPEGylation**", based on the conjugation of small molecules with very low molecular weight PEG.

CT327, a 2 kDa PEG derivative of K252a, has shown very high efficacy in animal models and an extremely favorable safety profile. It has displayed strong antiproliferative activity on keratinocytes by inhibiting the kinase activity of NGF receptor TrkA. The remarkable kinase

selectivity is the basis of the demonstrated negligible toxicity of **CT327**.

The new drug has also shown very low or minimal systemic absorption after dermal administration. The target profile of the desirable topical drug has thus been fully met. **CT327** is intended to be used for the topical treatment of psoriasis, dermatitis, and other pathologies related to keratinocyte hyperproliferation.

Psoriasis and dermatitis are relevant skin disorders, impacting also patient's quality of life. These pathologies have a prevalence of over 3% of the population with different levels of severity. All the patients, even those treated with biologics, need topical treatment: practically 95% of patient population use topical drugs.

CT327 then represents a very promising drug with a highly competitive position versus the current treatments.

S. Fumero, CEO of CREABILIS therapeutics, commented: "The approval to enter Clinical Trial of **CT327** is an important achievement for **CREABILIS**. Considering that we received the precursor molecule (K252a, kindly offered by Cephalon Inc. under MTA) in November 2005, we have completed the entire development for approval in 18 months. This demonstrates the high efficiency and capability of **CREABILIS** team to manage and coordinate the drug development process. We expect to enter Phase I Clinical Trial in the UK very soon".

S. Traversa, CSO of CREABILIS therapeutics, said: "This is the first successful outcome of our **MiniPEGylation technology**. We have other miniPEGylated derivatives in our R&D pipeline and we strongly believe that they will reach similar successful achievements based on their high kinase selectivity and outstanding drugability".

F. Conicella, General Manager of the Bioindustry Park del Canavese, said: "I am very proud of this important result, because **CT327** is the first candidate drug discovered and developed inside the Park facilities. The scientific and technical support of the Park has been certainly instrumental to the speed of development by which **CREABILIS** has brought its molecule to clinical stage".

About CREABILIS therapeutics SpA

CREABILIS therapeutics is an Italian biopharmaceutical company discovering and developing new therapeutic candidates for skin

pathologies and related conditions with significant unmet medical needs. Founded in 2003, **CREABILIS** is located in the Bioindustry Park del Canavese, with a subsidiary laboratory in Milano (Centro Cardiologico Monzino). **CREABILIS therapeutics** is today strongly committed to exploit the potential of its discovery assets and its know-how in the fields of inflammation, kinase inhibition, and cytokine-chemokine networking, especially in, but not limited to, dermal pathologies.

CT327 is the most advanced project entering now Phase I. The early stage of this project was partially funded by Regione Piemonte. Business development of **CT327** is supported by Bio3 Reasearch, Milano. A second preclinical stage asset, derived by the application of the **MiniPEGylation technology (CT335)**, is under development for the treatment of Behçet's Disease as orphan drug. A third preclinical stage project, in collaboration with Nautilus Biotech (Paris), is a mutated HMGB1 Box A for the systemic treatment of infectious skin disorders and Systemic Lupus Erythematosus. For more information, please visit: www.creabilistherapeutics.com

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