DAC

DAC s.r.l. Initiates Phase I/IIa Clinical Trial For DAC-0060 To Treat Nonmelanoma Skin Cancers

Milan (Italy), 28 Oct 2008 ---- DAC s.r.l., a fully owned subsidiary of Genextra S.p.A. developing novel therapeutics that inhibit histone deacetylases (HDACs) and other oncological targets to treat solid and hematological cancers, today announced the initiation of a Phase I/IIa clinical study of topical HDAC inhibitor DAC-0060, its lead compound for treating nonmelanoma skin cancers such as basal cell carcinoma, squamous cell carcinoma and potentially actinic keratosis, a precancerous condition of the skin that often progresses into squamous cell carcinoma. The trial is a single-arm, open-label, phase I/IIa study to evaluate recommended dose (RD), by safety and tolerability parameters evaluation; and to investigate early signs of anti-tumor activity and pharmacodynamic/pharmacokinetic properties of DAC-0060 after topical application. This clinical trial is the first-in-human study in the global development of DAc-0060 and will be conducted in Italy.

“The wide recognition of HDACs as promising targets for therapeutic interventions for cancer has led to test many structurally different HDAC inhibitors in human patients; DAC-0060 showed inhibitory activity towards different HDACs providing an activity profile highly supportive of its clinical development for the treatment of NMSC.” Said Saverio Minucci, DAC’s CSO.

“There is a tremendous unmet medical need to treat patients affected by NMSC given the considerable limitations of current topical treatments - such as low compliance, high risk of recurrence, local side effects - and the incredible benefit of a topical treatment vs surgical intervention” said Paolo Fundarò, Chief Executive Officer of DAC, “Entering into human trials with DAC-0060 is an important milestone for DAC, only four years after beginning our activities.”

About DAC-060

DAC-0060 is a fully synthetic, topically applied small molecule derived from a novel chemical scaffold. DAC-0060 is a potent pan-HDAC inhibitor. In preclinical studies, DAC-0060 has shown a strong antiproliferative effect on tumor cells, correlated to a clear induction of cell death through apoptotic mechanisms. Anti-tumor activity was observed in preclinical animal model.

About Nonmelanoma Skin Cancer

Two of the most common forms of skin cancer, basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), are collectively known as nonmelanoma skin cancer. BCC and SCC develop in the epidermal layer of the skin, usually as the result of repeated exposure to UV radiation. The vast majority of NMSC is basal cell carcinoma which comprises 75% of all NMSC cases and represents the most frequent human cancer. Squamous-cell carcinoma accounts for 20% of NMSC cases. The treatment of choice is surgical excision; however, this treatment often leaves disfiguring scars. In consideration of the low degree of malignancy, several local treatments have been introduced, however, although efficacious, they are hampered by low compliance, high risk of recurrence of the disease and by local side effects that limit their clinical use.

About DAC s.r.l.

DAC s.r.l. is a privately held biopharmaceutical company committed to the discovery and development of novel cancer therapeutics. In addition to topical DAC-0060, the company is advancing through preclinical development product candidates that inhibit HDAC and HSP90 via systemic route. DAC is fully owned by Genextra S.p.A., a private biopharmaceutical group headquartered in Milan primarily dedicated to the discovery and development of innovative therapeutics for the cure of cancer, age-related and metabolic disorders. Beyond DAC, Genextra develops its programs through three other subsidiary companies: Congenia, Tethis and Intercept Pharmaceuticals.