

## ActoGeniX obtains IND approval

The United States' Food and Drug Administration (FDA) has approved ActoGenix's Investigational New Drug (IND) application for AG013, a novel therapeutic product for the treatment of oral mucositis in cancer patients. This IND application approval allows ActoGeniX to initiate a phase 1B clinical trial with AG013, which will now become the second clinical development program in ActoGeniX's portfolio. Oral mucositis is a painful inflammation of the oral mucosa affecting cancer patients and making daily activities such as eating, drinking and talking difficult or impossible. It is a severe and debilitating disease for which no effective cure is available today. AG013 is based on ActoGeniX's proprietary TopAct<sup>®</sup> platform and constitutes of an oral rinsing solution that delivers a potent healing factor to the damaged mucosa in the oral cavity. In preclinical pharmacology studies AG013 has already shown significant efficacy results suggesting that it holds great promise for the treatment of oral mucositis in cancer patients. ActoGeniX's phase 1B clinical study will be conducted in six major oncology centers in the US, and will mainly evaluate safety and tolerability of the new product, but will also allow the collection of efficacy data. 21 Patients will be included in this placebo-controlled, single blinded, dose escalation study, which is expected to be completed during the first half of 2010. Dr. Mark Vaeck, CEO of ActoGeniX, commented: "We are extremely pleased with this approval by the FDA, which is a clear endorsement of the quality of our preclinical data package and development plan for AG013. Oral mucositis is a very significant and underserved opportunity in the cancer supportive care market, and a novel therapeutic product in this area has huge commercial potential." Dr. Bernard Coulie, Chief Medical Officer of ActoGeniX, added: "With the advancement into clinical development of AG013, our second lead product, ActoGeniX is well on its way to effectively build a significant clinical-stage product pipeline. Moreover AG013 could become the first approved therapy for oral mucositis in patients undergoing treatment of solid tumors or head/neck cancers."