NEW YORK (GBI Research), 16 July 2012 - **Epigenetics** is emerging as a key determinant of **cellular differentiation**, playing a vital role in a number of human diseases, according to a new report by pharmaceutical experts GBI Research.

The new report* examines epigenetics, which refers to a selective regulation of gene expression within different cells that does not affect the genomic makeup of the Deoxyribonucleic Acid (DNA) sequence.

The last few years have seen a surge in research into epigenetic modification of the chromatin within a cell's genome. Epigenetic changes appear to regulate differentiation of stem cells as well as giving rise to malignant cells, which include cancerous cells. Given the huge market potential and considerable unmet need, it is unsurprising that almost every major pharmaceutical company has an epigenetic program in oncology. The growing number of cancer patients worldwide offers a lucrative market for epigenetic-based molecules, and the successful launch of just one drug could generate huge revenues.

Despite the field's optimism and the boom in epigenetic research over the last decade, however, several critical challenges need to be addressed before epigenetics is seen as a viable treatment option and a potential business investment.

Epigenetic targets are structurally complex, requiring a great deal of work to be characterized, and investigations into innovative drug discovery against new targets involve a high level of risk. The toxicity of epigenetic-derived drugs is an important challenge for researchers and investors, as currently marketed epigenetic-based drugs can cause serious adverse effects, and these risks have led to a low uptake of epigenetic therapies in the market.

It also remains unknown as to why first-generation epigenetic-based therapies have been particularly successful against hematological cancers in contrast to other types, especially solid tumors, and the unknown mechanism of action is daunting for researchers and pharmaceutical

industries worldwide. Despite extensive research, very few targets have been identified, and so a great deal of work is still necessary to characterize and understand the consequences of their actions. Little is known about the chromatin modifications in cancer, or the mechanisms by which epigenomes influence the pathogenesis of various disease conditions.

GBI Research believes that these challenges will not be resolved by a single organization, but instead demand coordinated and collaborative efforts from academia and pharmaceutical companies over time, in order to solve this medical mystery.