

## Hy BioPharma Enters Phase III Development with its Lead Drug Hypericin for Topical Phototherapy of Skin Lymphoma

**29.05.2008** - Hy BioPharma Inc., a US and Israeli early stage biopharmaceutical company that is developing and commercializing an innovative drug technology focused on the treatment of cancer, autoimmune disorders, and inflammation, announced that it is entering Phase III clinical development, with its lead product hypericin for topical phototherapy of CTCL.

The company has successfully completed its End of Phase II meeting with the FDA and is moving into Phase III development for topical phototherapy of the blood cell skin lymphoma, cutaneous T-cell lymphoma (CTCL) which forms cancer lesions in the skin. The FDA has accorded hypericin orphan drug status for the CTCL indication, thereby providing Hy BioPharma the opportunity to rapidly complete Phase III requirements for filing a new drug application (NDA) to gain marketing approval.

"We are very pleased with the outcome of the End of Phase II meeting with the FDA, and the Company is currently working with the Oncology Division of the FDA to finalize the Phase III Clinical Protocol," said Dr. Alfonso Tobia, President of Hy BioPharma.

The Phase II trial was conducted in the US at several medical centers including the University Of Pennsylvania School Of Medicine in Philadelphia, MD Anderson Cancer Clinic in Houston, and Case Western Medical Center in Cleveland. Hypericin is applied topically as an ointment and photo-activated with natural light twice weekly for 6 weeks. "We expect to initiate the Phase III trial later this year and we anticipate approximately 2 years until its completion," said Dr. Tobia.

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