Biovest: FDA Grants Orphan Drug Status for BiovaxID (Phase II), a Personalized Cancer Vaccine Targeting Mantle Cell Lymphoma

Biovest today (7/26) announced that the U.S. FDA has granted Orphan Drug Designation to BiovaxID, Biovest`s personalized cancer vaccine for mantle cell lymphoma. The FDA previously granted Orphan Drug Designation for BiovaxID for the treatment of indolent follicular non-Hodgkin`s lymphoma. BiovaxID represents a new class of active immunotherapy and is one of the few select late-stage, patient-specific cancer vaccines vying to be among the first to reach market.

With FDA Orphan Drug Status granted for this second indication, Biovest gains seven-years of market exclusivity for BiovaxID upon approval for the treatment of mantle cell lymphoma and/or indolent follicular lymphoma, thereby offering competitive protection from similar drugs of the same class.

According to Biovest's Vice President, Product Development & Regulatory Affairs, Dr. Carlos F. Santos, "With promising clinical trials now complete in both follicular lymphoma and mantle cell lymphoma, we are preparing to seek regulatory approvals for BiovaxID in two separate indications. In addition to our ongoing regulatory efforts with regard to follicular lymphoma, we look forward to formally presenting our mantle cell Phase II clinical trial results to the FDA, and potentially the EMEA, later this year, as we explore potential expedited market registration pathways to offer this therapeutic vaccine regimen as a new treatment option for mantle cell patients."

In the BiovaxID's Phase II study for mantle cell lymphoma, tumor-specific immune responses were observed in 87% of the patients vaccinated with BiovaxID following rituximab-containing chemotherapy (EPOCH-R). Consistent with all other BiovaxID studies, the vaccine was very well tolerated and safe.

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Oncology Indication: Lymphoma
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