

Press Release

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Epiphany Announces Positive Results from its Phase 2b trial in shingles

SAN FRANCISCO, CA, November 18, 2009 – Epiphany Biosciences announced results from its Phase 2b dose-ranging study of EPB-348 (valomaciclovir) in patients with shingles (herpes zoster) infection. The study's primary endpoint was non-inferiority of once-daily valomaciclovir compared to thrice-daily valacyclovir in terms of time to complete crusting of the shingles rash. The double-blinded study enrolled 373 patients, randomized into 3 arms: 1 gram of once-daily EPB-348, 2 grams of once-daily EPB-348, thrice-daily valacyclovir (1 gram, three times per day). Eighteen patients also received 3 grams of once-daily EPB-348.

Once-daily EPB-348 at two grams met its primary endpoint of non-inferiority to valacyclovir. Valomaciclovir (EPB-348) was also non-inferior to valacyclovir in the secondary endpoints of time to complete pain resolution, time to rash resolution and time to cessation of new lesion formation. The highest dose of valomaciclovir (3 grams once daily) demonstrated superiority to valacyclovir with regards to the primary endpoint (p-value < 0.007).

Dose-dependent trends to improved pain resolution in the subset of treated patients who were over 50 years old and trends to faster resolution of severe pain in patients of all ages were seen in the higher dose EPB-348 treatment arms when compared to valacyclovir. All doses of EPB-348 showed improvement over valacyclovir for patients presenting for first treatment towards the end of the 72 hour treatment window. Currently-approved shingles treatments are effective only within the first 72 hours of rash appearance.

"These Phase 2 data indicate that once-daily valomaciclovir could be more convenient than three times daily valacyclovir for the treatment of herpes zoster, and it is equally safe. Moreover, the 3 gram dose of valomaciclovir was superior to valacyclovir in terms of clinical efficacy. Therefore, Phase 3 studies with larger numbers of patients are clearly indicated," said Stephen Tyring, MD, PhD, Clinical Professor at the University of Texas Health Sciences Center, the lead investigator of the study.

There were no differences in significant adverse events between valomaciclovir and valacyclovir groups. The most common adverse event in all patient groups was nausea. No patient discontinued treatment due to adverse events related to EPB-348 use.

“We are pleased with our Phase 2b results that demonstrate once-daily EPB-348 is both safe and active in treating shingles. We are encouraged by the trends to better pain resolution and less severe pain in the valomaciclovir-treated patients. We anticipate that EPB-348 may be the first once-a-day shingles drug with a wider treatment window and a reduction in both the incidence and severity of shingles associated pain. We look forward to demonstrating these and other additional benefits in Phase 3 clinical trials,” said Fred Volinsky, MD, Epiphany Biosciences' CEO.

EPB-348 has also been shown to be effective against acute infectious mononucleosis, for which there is no FDA-approved treatment, in a Phase 2a study. Data from this study were presented during the 2009 ICAAC meeting in San Francisco.

About EPB-348

EPB-348 is a potent inhibitor of herpes viruses, including the varicella zoster and Epstein-Barr viruses licensed from the Swedish biotech company Medivir AB. It has been studied clinically in both shingles and infectious mononucleosis.

About Shingles

Shingles is a reactivation of the varicella zoster virus, the same virus that causes chickenpox in children, and infects over 90% of the US adult population. An estimated 5 in 1000 people suffer from shingles in the US every year, and 20% of all individuals are estimated to experience at least one episode of shingles during their lifetime. The risk of shingles outbreak dramatically increases with age.

Shingles manifests itself as a painful rash that develop into blisters, often mainly on one side of the body. The normal healing process takes about four weeks. Shingles pain is frequently observed as zoster associated pain (ZAP) and post-herpetic neuralgia (PHN). ZAP is present during the initial disease outbreak. PHN is a persistent pain that is present in some patients long after the lesions have resolved.

About Epiphany Biosciences

Epiphany Biosciences is a privately-held company developing therapeutic products and diagnostic technologies that treat or help prevent the spread of pathogenic viruses, including varicella zoster virus (VZV), Epstein-Barr Virus (EBV) and hepatitis C virus (HCV).

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