OBI Pharma to Unblind its Phase 2/3 Clinical Trial of OBI-822 Active Immunotherapy for Metastatic Breast Cancer by March 2016

TAIPEI, TAIWAN, August 31/ -- OBI Pharma, Inc., a Taiwan biotech company (TPex: 4174), announced it plans to unblind its flagship OBI-822/821 (formerly OPT-822/OPT-821) Phase 2/3 clinical trial (Protocol Number OPT-822-001) by March 2016. This decision is based on the recommendations made at its Expert Meeting, held on Friday, 28 August 2015.

"The recruitment of 349 patients for this trial was completed on 25 August 2014," explained Amy Huang, General Manager of OBI Pharma, Inc. (OBI) Upon the experts' review, the data of the trial was found to be approaching maturity. "OBI's intention is to formally present our trial results at an international oncology conference in 2016."

OBI's Chief Medical Officer, Dr Nathan Chen, commented that immunotherapy has now entered the mainstream of cancer treatment. Being the first active immunotherapy to target breast cancer, OBI-822 has drawn a lot of attention in the field. OBI-822 was exclusively licensed from the Memorial Sloan-Kettering Cancer Center (MSKCC) in New York. The cancer therapeutic vaccine targets Globo H, an oligosaccharide tumor antigen, triggering the immune system to generate antibodies that activate cytotoxic T cells and destroy cancer cells.

Clinical Study Design

The Phase 2/3 randomized controlled trial (RCT) was initiated in December, 2010, with an enrollment target of 342 subjects; the actual recruitment number was 349 subjects. The study enrolled female subjects with metastatic breast cancer who achieved stable disease (SD), partial response (PR), or complete response (CR) after at least 1 regimen of anticancer therapy. Patients were recruited from 45 medical centers in Taiwan, Hong Kong, the US, Korea and India. Subjects were randomized to receive either active treatment (OBI-822/821) plus cyclophosphamide or control (PBS) plus cyclophosphamide in a 2:1 allocation.

About OBI-822

OBI-822 is a new, investigational anti-cancer treatment that belongs to a novel class of active immunotherapies. It is a synthetic glycoprotein comprised of a Tumor-Associated Carbohydrate Antigen (TACA), Globo H, covalent bounded to a carrier protein, Keyhole Limpet Hemocyanin. OBI-821 is a saponin-based adjuvant. Globo H is expressed in high levels on the surface of malignant tumors in many epithelial cancers, such as breast, prostate, gastric, lung, colon, pancreatic, and ovarian cancer, etc. The immunogenicity of the antigen is enhanced by conjugating Globo H to the KLH carrier protein to form OBI-822 (Globo H-KLH), and co-administered with an adjuvant, OBI-821.

About OBI Pharma

OBI Pharma, Inc. is a Taiwan biopharmaceutical company established in 2002. OBI's mission is to develop novel therapeutic agents for unmet medical needs, including

cancer & infectious diseases. The company's flagship product is OBI-822, a first-in-class active immunotherapy for metastatic breast cancer. OBI is also developing next generation active immunotherapies for difficult to treat cancers, including lung, prostate, pancreatic, stomach, and ovarian. The company is the license holder for DIFICID™ in Taiwan and owns the commercial rights to the product, a novel antibiotic indicated for C. difficile-associated diarrhea. Additional information can be found at www.obipharma.com/en

Forward-looking Statements

Statements included in this press release that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about future clinical trials, results and the timing of such trials and results. Such risk factors are identified and discussed from time to time in OBI Pharma's reports and presentations, including OBI Pharma's most recent filings with the Taiwan Securities and Exchange Commission.

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