# Shanghai Escugen Biotechnology Co., Ltd., a partner of Levena Biopharma, a Sorrento Company, releases positive results from a first-in-human study of ESG401, a TROP2 Antibody Drug Conjugate in patients with locally advanced/metastatic solid tumors at the

June 5, 2023

CHICAGO, June 05, 2023 (GLOBE NEWSWIRE) -- Shanghai Escugen Biotechnology Co., Ltd. (“Escugen”), a partner of Levena (Suzhou) Biopharma Co., Ltd. (“Levena”), a wholly owned subsidiary of Sorrento Therapeutics, Inc. (Sorrento), today released preliminary results from a first-in-human study of ESG401, a trophoblast cell-surface antigen 2 (TROP2) antibody drug conjugate (ADC), in patients with locally advanced/metastatic solid tumors at the 2023 Annual Meeting of ASCO, the American Society of Clinical Oncology, held June 2-6 in Chicago, IL. ESG401 is an innovative ADC developed by Escugen and Levena. Escugen and Levena Biopharma jointly own the domestic and international patents of this ADC and share global rights for the product. ESG401 is composed of a humanized anti-Trop2 IgG1 monoclonal antibody (mAb) conjugated to a topoisomerase I inhibitor SN38 via a proprietary stable covalent linker with a drug antibody ratio (DAR) of 8. ESG401 has potential differentiated advantages over its competitors in terms of safety, effectiveness and process robustness. Using an innovative, highly stable and cleavable linker, this ADC demonstrated that it releases very little free toxin during circulation, which may reduce off target toxicity in a series of preclinical studies. Additionally, premature release of the mAb may compete for binding sites with the ADC to reduce its efficacy. The ADC highly enriches in tumor tissues and rapidly endocytoses, thereby effectively killing tumor cells and inhibiting tumor growth.

In the Phase I study, adult ESG401 patients with locally advanced/metastatic solid tumors refractory to or relapsed from standard treatments with measurable disease (RECIST v1.1) were eligible. ESG401 was administered by IV infusion initially in an ascending dose safety study by designated dose and regimen until unacceptable toxicity or progressive disease and followed by expansion cohorts. The Bayesian Optimal Interval (BOIN) design was used to establish the maximum tolerated dose (MTD). As of February 3, 2023, 35 heavily pretreated patients with a median age of 53 years were treated with at least one dose of ESG401 during dose escalation, 2 to 20 mg/kg administered every 3 weeks (Regimen A), or 12 to 16 mg/kg on day 1, 8, and 15 in a 4-week cycle (Regimen B). Eighty percent of the patients had an ECOG status of 1. Sixty-three percent of the patients had received at least 3 lines of prior therapy and overall the number of lines of prior therapy was a median of 4 (range 2-10). A total of 94% of patients had visceral metastases (11% brain, 63% liver, 60% lung) at baseline. From the ASCO poster, patient demographics and baseline characteristics is shown below:

| Parameter | Regimen A[b] | | | | Regimen B[b] | | | Total (N=35) |
|---|---|---|---|---|---|---|---|---|
| | 8mg/kg (N=3) | 12mg/kg (N=4) | 16mg/kg (N=5[a]) | 20mg/kg (N=5) | 12mg/kg (N=5) | 14mg/kg (N=6) | 16mg/kg (N=7) | |
| Female sex, n(%) | 3 (100%) | 4 (100%) | 5 (100%) | 5 (100%) | 5 (100%) | 6 (100%) | 7 (100%) | 35 (100%) |
| Age, y, median (range) | 63 (51,66) | 41 (32, 43) | 58 (38, 69) | 53 (33, 70) | 56 (47, 67) | 40 (34, 56) | 56 (40, 67) | 53 (32, 70) |
| Histology, n(%) | | | | | | | | |
| Endometrial Carcinoma | 0 | 0 | 1 (20%) | 0 | 0 | 0 | 0 | 1 (3%) |
| Triple Negative Breast Cancer | 2 (67%) | 3 (75%) | 3 (60%) | 3 (60%) | 3 (60%) | 1 (17%) | 1 (14%) | 16 (46%) |
| HR+/HER2- Breast Cancer | 1 (33%) | 1 (25%) | 1 (20%) | 2 (40%) | 2 (40%) | 4 (67%) | 5 (71%) | 16 (46%) |
| HR-/HER2+ Breast Cancer | 0 | 0 | 0 | 0 | 0 | 1 (17%) | 1 (14%) | 2 (6%) |
| ECOG PS, n(%) | | | | | | | | |
| 0 | 1 (33%) | 0 | 1 (20%) | 2 (40%) | 0 | 0 | 3 (43%) | 7 (20%) |
| 1 | 2 (67%) | 4 (100%) | 4 (80%) | 3 (60%) | 5 (100%) | 6 (100%) | 4 (57%) | 28 (80%) |
| Visceral metas at baseline, n (%) | | | | | | | | |
| Brain metas | 0 | 1 (25%) | 0 | 1 (20%) | 1 (20%) | 0 | 1 (14%) | 4 (11%) |
| Liver metas | 1 (33%) | 3 (75%) | 2 (40%) | 2 (40%) | 4 (80%) | 4 (67%) | 6 (86%) | 22 (63%) |
| Lung metas | 1 (33%) | 3 (75%) | 4 (80%) | 4 (80%) | 4 (80%) | 3 (50%) | 2 (29%) | 21 (60%) |
| Prior therapies in metastatic setting | | | | | | | | |
| median (range) | 1 (1, 2) | 5 (3, 7) | 5 (1, 6) | 2 (2, 11) | 9 (4, 12) | 4 (3, 9) | 6 (2, 10) | 4 (1, 12) |

a Include pts who were assigned to 2mg/kg (N=1) and 4mg/kg Q3W (N=1) while eventually, intra-pt escalated to 16mg/kg Q3W.
b Regimen A=Q3W, Regimen B=D1,8,15 in a 4-week cycle

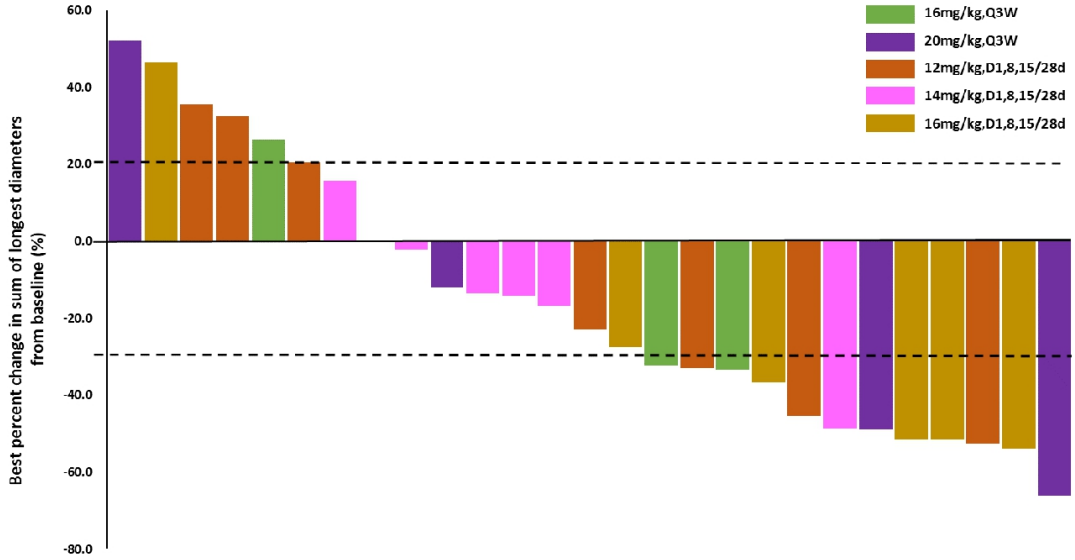
A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/bbc508be-c81f-4493-90e9-e6dc146cb70a

While one patient at 20 mg/kg reported a dose limiting toxicity (grade 4 neutropenia and grade 3 febrile neutropenia), the MTD was not reached. The most common treatment-related adverse events were leukopenia, neutropenia, anemia, fatigue and nausea or vomiting. The most common grade 3 events were leukopenia (29%) and neutropenia (31%) with no grade 3 thrombocytopenia, diarrhea, skin rash or oral mucositis. There was no evidence of interstitial lung disease. The frequency of TEAEs > 15% regardless of causality is shown below.

| TEAE, n(%) | N=35 | |
|---|---|---|
| | All grades | Grade ≥3 |
| Any TEAE | 33 (94.3) | 15 (42.9) |
| TEAE, by preferred term (in ≥15% of patients) | | |
| Leukopenia | 28 (80.0) | 10 (28.6) |
| Neutropenia | 24 (68.6) | 11 (31.4) |
| Anemia | 23 (65.7) | 1 ( 2.9) |
| Fatigue | 19 (54.3) | 0 |
| Nausea | 18 (51.4) | 0 |
| Vomiting | 17 (48.6) | 0 |
| Diarrhea | 11 (31.4) | 0 |
| Pyrexia | 10 (28.6) | 0 |
| Decreased appetite | 9 (25.7) | 0 |
| Thrombocytopenia | 7 (20.0) | 0 |
| Alopecia | 7 (20.0) | 0 |
| Cough | 6 (17.1) | 0 |

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/758ccb85-a5f2-4edb-a877-340b31789fe9

Of the 33 efficacy evaluable patients, 12 achieved partial responses and 4 achieved stable disease lasting at least 24 weeks. The dose of 16 mg/kg was identified as the therapeutically relevant dose. The overall response rate and disease control rate were 36% (4 of 11 patients) and 64% (7 of 11 patients), respectively, in patients with triple negative breast cancer, and 62% (8 of 13 patients) and 77% (10 of 13 patients), respectively, in patients who were HR+/HER2- breast cancer. Three patients have been on treatment for at least 12 months. These data demonstrate that ESG401 is well tolerated and demonstrates efficacy in heavily pretreated patients. Additional studies are ongoing with this innovative promising treatment. A waterfall plot of the data demonstrating the best % change in sum of longest dimension in target lesions from baseline is shown below for patients who received the therapeutic relevant dose (16 mg/kg).

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**About Escugen Biotechnology Co., Ltd.**

Escugen Biotechnology Co., Ltd. is a clinical-stage biotechnology company committed to developing and commercializing innovative drugs for the treatment of cancer, autoimmune disease and other diseases with unmet medical needs. The company's leading programs include ESG401, an anti-Trop2 antibody drug conjugate, currently in Phase Ib/II clinical trials in patients with locally advanced/metastatic solid tumors, and ESG206, an anti-BAFFR monoclonal antibody, currently in Phase I study in subjects with B-cell Lymphoid Malignancies.

**About Sorrento Therapeutics, Inc.**

Sorrento is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease, and COVID-19. Sorrento's multimodal, multipronged approach to fighting cancer is made possible by its extensive immuno-oncology platforms, including key assets such as next-generation tyrosine kinase inhibitors ("TKIs"), fully human antibodies ("G-MAB™ library"), immuno-cellular therapies ("DAR-T™"), antibody-drug conjugates ("ADCs"), and oncolytic virus ("Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including STI-1558 and COVI-MSC™, and diagnostic test solutions, including COVIMARK™.

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a TRPV1 agonist, non-opioid pain management small molecule, resiniferatoxin (“RTX”), and SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXA™), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and to commercialize ZTlido® (lidocaine topical system) 1.8% for the treatment of postherpetic neuralgia (PHN). RTX has been cleared for a Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. Positive final results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. ZTlido® was approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.com

**Forward-Looking Statements**

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sorrento Therapeutics, Inc., under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding Sorrento’s products, technologies and prospects, the development of and prospects for ESG401 and ESG401’s potential advantage over any competitive products in terms of safety, effectiveness and process robustness. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: risks related to Sorrento's technologies and prospects, including, but not limited to risks related to safety and efficacy of ESG401and seeking regulatory approval for ESG401; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risk of difficulties or delays in obtaining regulatory approvals; risks that clinical study results may not meet any or all endpoints of a clinical study and that any data generated from such studies may not support a regulatory submission or approval; risks that prior test, study and trial results, including those for ESG401, may not be replicated in continuing or future studies and trials; risks of manufacturing and supplying drug product; risks related to leveraging the expertise of its employees, subsidiaries, affiliates and partners to assist Sorrento in the execution of its product candidates’ strategies; risks relating to the voluntary proceedings under Chapter 11 in the Bankruptcy Court (the "Chapter 11 Cases"), Sorrento's ability to continue operating in the ordinary course while the Chapter 11 Cases are pending, the timing and outcome of the Chapter 11 Cases, Sorrento's ability to obtain timely approval by the Bankruptcy Court of the motions filed in the Chapter 11 Cases, employee attrition and Sorrento's ability to retain senior management and other key personnel due to the distractions and uncertainties of the Chapter 11 Cases, Sorrento's ability to maintain relationships with suppliers, customers, employees and other third parties and regulatory authorities as a result of the Chapter 11 Cases, the Bankruptcy Court's rulings in the Chapter 11 Cases, the length of time that Sorrento will operate under Chapter 11 protection and the continued availability to Sorrento of operating capital during the pendency of the Chapter 11 Cases, risks associated with any third party motions in the Chapter 11 Cases, increased administrative and legal costs related to the chapter 11 process, exposure to potential litigation and inherent risks involved in a bankruptcy process, the potential adverse effects of the Chapter 11 Cases on Sorrento's liquidity or results of operations, or Sorrento's ability to timely file its periodic reports or meet periodic reporting requirements with the SEC; and other risks that are described in Sorrento's most recent periodic reports filed with the Securities and Exchange Commission, including Sorrento's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, including the risk factors set forth in those filings. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release except as required by law.

**Media and Investor Relations**

Contact: Brian Cooley

Email: mediarelations@sorrentotherapeutics.com



**Figure 1**

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**Sorrento Therapeutics, Inc.**

**Figure 2**

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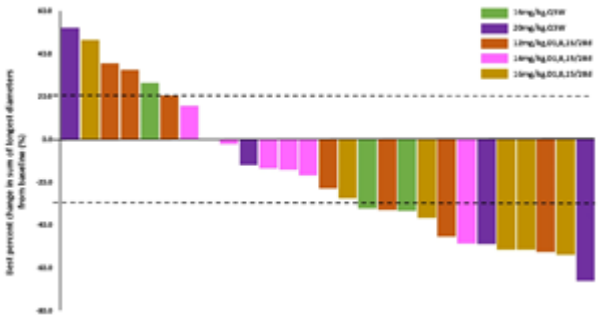
**Sorrento Therapeutics, Inc.**

**Figure 3**



**Sorrento Therapeutics, Inc.**