BIOZEUS ANNOUNCES BREAKTHROUGH PHASE II RESULTS IN FEMALE SEXUAL AROUSAL AND INTEREST DISORDER (FSIAD)

PHASE 2 CLINICAL TRIAL IN WOMEN WITH FEMALE SEXUAL INTEREST/AROUSAL DISORDER (FSIAD) IS CONCLUDED WITH BREAKTHROUGH RESULTS

****RIO DE JANEIRO, BRAZIL – SEPTEMBER 11, 2025****

BIOZEUS BIOPHARMACEUTICALS S.A. IS PLEASED TO ANNOUNCE THE SUCCESSFUL COMPLETION OF ITS PHASE II CLINICAL TRIAL EVALUATING THE BZ371A EFFICACY, SAFETY AND TOLERABILITY IN WOMEN WITH FSIAD.

THE STUDY MET ITS PRIMARY ENDPOINTS AND ACHIEVED ALL PRE-DEFINED DEVELOPMENT MILESTONES, CONFIRMING BOTH THE SAFETY AND EFFICACY OF BZ371A IN THIS HIGH-NEED POPULATION.

PHASE 2 CLINICAL TRIALS ANALYZED WOMEN WITH LOW SEXUAL AROUSAL AND INTEREST – BEFORE TREATMENT, WOMEN WERE SATISFIED WITH THE LEVEL OF AROUSAL AND INTEREST IN ONLY 54% AND 46% OF THE SEXUAL ENCOUNTER, RESPECTIVELLY.

AFTER 14 DAYS OF BZ371A USE, SATISFACTION WITH LEVEL OF AROUSAL AND INTEREST INCREASED TO 86% AND 62% RESPECTIVELLY ($P<0.05$ IN BOTH, STATISTICALLY SIGNIFICANT). PLACEBO USE WAS NOT DIFFERENT FROM BASELINE VALUES.

BZ371A IS ALSO EFFECITVE IN OTHER SEXUAL MARKERS SUCH AS LUBRIFICATION, LACK OF PAIN AND GENERAL SEXUAL SATISFACTION.

BZ371A IS EFFECITVE IN ALL FSIAD SUBPOPULATIONS: PRE AND POSTMENOPAUSAL WOMEN, WITH OR WIHTOUT ESTROGEN USE.

THERE WERE NO SEVERE ADVERSE EVENTS WITH BZ371A, NO EVENTS LED TO DRUG DISCONTINUATION, AND NO CLINICALLY SIGNIFICANT ABNORMAL FINDINGS WERE OBSERVED IN GENERAL OR GYNECOLOGICAL PHYSICAL EXAMINATIONS AFTER DRUG ADMINISTRATION. LOCAL COMPLAINTS WERE SIMILAR TO PLACEBO.

**** BZ371A: A NEW AND DEFINITIVE SOLUTION FOR SEXUAL DYSFUNCTION IN MEN AND WOMEN ****

BZ371A IS A FIRST-IN-CLASS THERAPEUTIC PEPTIDE DERIVED FROM A NEW CLASS OF NITRIC OXIDE SYNTHASE (NOS) ENHANCERS.
BZ371A IS A NON-HORMONAL, NON-CENTRAL NERVOUS SYSTEM DRUG, THAT TOPICALLY APPLIED, INDUCES LOCALIZED VASODILATION AND INCREASED BLOOD FLOW WITHOUT SYSTEMIC EXPOSURE OR THE NEED FOR EXTERNAL STIMULI,
WITH A FAVORABLE SAFETY PROFILE DEMONSTRATED IN BOTH PRECLINICAL AND CLINICAL STUDIES.

BZ371A PROVED TO BE EFFECTIVE IN MEM WITH PROSTATE CANCER SUBMITTED TO RADICAL PROSTATECTOMY. NERVE DAMAGE JEOPARDIZES SEXUAL STIMULI AFTER SURGERY, AND EXISTING DRUGS ON THE MARKET PROVIDE LITTLE TO NO EFFECT IN FACILITATING SEXUAL REHABILITATION.
BZ371A WAS EFFECTIVE WITH ONLY ONE MONTH OF TREATMENT, SUPERIOR TO DAILY TADALAFIL. BZ371A MAY BE THE ONLY DRUG ABLE TO MAINTAIN PENILE INTEGRITY POST RADICAL PROSTATECTOMY, ALLOWING SEXUAL REHABILITATION WITHOUT SYSTEMIC SIDE EFFECTS.

MORE THAN 95% OF FEMALE SEXUAL DISFUNCTION (FSD) SUFFERERS HAVE NO TREATMENT. FSIAD ACOOUNTS FOR 65% OF ALL FSD SUFFERERS.
MOST SOLUTIONS ARE HORMONAL BASED FOR POSTMENOPAUSAL WOMEN AND CENTRAL NERVOUS SYSTEM DRUGS FOR PREMENOPAUSAL WOMEN, WITH LIMITED EFFICACY AND SYSTEMIC SIDE EFFECTS.
BZ371A REPRESENTS A POTENTIALLY TRANSFORMATIVE SOLUTION FOR PATIENTS WITH LIMITED TREATMENT OPTIONS.

****KEY FACTS****

- PHASE 1 RESULTS CONFIRMED THE SAFETY, TOLERABILITY, AND LACK OF SYSTEMIC EXPOSURE OF BZ371A WHEN APPLIED TOPICALLY IN MEN AND WOMEN.
- PHASE 2 IN MEN CONFIRMED THE EFFICACY, SAFETY AND TOLERABILITY OF BZ371A IN PROSTATE CANCER POST RADICAL PROSTATECTOMY.
- PHASE 2 IN WOMEN CONFIRMED THE EFFICACY, SAFETY AND TOLERABILITY OF BZ371A IN WOMEN WITH FSIAD.

****ABOUT BIOZEUS BIOPHARMACEUTICALS S.A.****

BIOZEUS IS A BRAZILIAN CLINICAL-STAGE BIOTECH COMPANY FOCUSED ON DEVELOPING A PLATFORM OF NEW THERAPEUTIC CLASS PEPTIDES.

THE COMPANY HAS RECENTLY ENTERED INTO AN AGREEMENT WITH ANOTHER DAY PHARMA LTD. (https://www.anotherdaypharma.com), A UK-BASED LEADER IN PERSONAL HEALTH INNOVATION. THIS PARTNERSHIP AIMS TO ACCELERATE THE GLOBAL REACH OF THIS GROUNDBREAKING THERAPEUTIC FOR BOTH MEN AND WOMEN.

****LICENSING OPPORTUNITY****

BIOZEUS IS COMMITTED TO MAKING ITS PRODUCTS AVAILABLE GLOBALLY. THE COMPANY IS ACTIVELY SEEKING PARTNERS INTERESTED IN ACQUIRING COMMERCIAL RIGHTS TO ITS PRODUCTS FOR VARIOUS MARKETS WORLDWIDE.

****CONTACTS FOR INQUIRIES, POTENTIAL PARTNERSHIPS, OR ADDITIONAL INFORMATION****

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