Press Release

IBSA USA Announces FDA Approval of VYBRIQUE™, the First and Only Oral Film to Treat Men with Erectile Dysfunction

- *Developed with IBSA's innovative FilmTec® technology that dissolves in the mouth without the need for food or water*
- *Approved in four dosage strengths (25, 50, 75, 100mg) for a tailored therapy to support the patient's needs*
- *Direct home delivery will be available in all states, providing patients a convenient fulfillment option*
- *U.S. Commercial availability anticipated in March 2026.*
- *Erectile dysfunction affects 30-50 million men in the US and is becoming more prevalent among men under 40*

Parsippany, NJ, February 5, 2026 – IBSA USA, the U.S. subsidiary of the Swiss pharmaceutical company IBSA, announced today that the Food and Drug Administration (FDA) has approved VYBRIQUE™, the first sildenafil oral film available to treat men aged 18 years and older with erectile dysfunction.

Erectile dysfunction (ED) impacts an estimated 30 to 50 million men in the U.S. and becomes more prevalent with age. However, ED is not limited to older populations; cases among younger men are on the rise[1]. This trend highlights the importance of proactive measures, including healthy lifestyle choices and regular physical activity, to help reduce the risk of developing ED[1].

VYBRIQUE is a discreet, easy-to-use, single-dose film that dissolves on the tongue without the need for water or other liquids, providing an on-the-go use option that may be taken anywhere from 30 minutes to 4 hours before sexual activity. VYBRIQUE can be taken with or without food.

"While awareness and open discussion around ED have grown, it's still a sensitive topic where many men value discretion," said Nicholas Hart, IBSA USA CEO. "The FDA approval of VYBRIQUE provides men experiencing ED with a novel treatment option that helps meet the evolving needs of patients today."

VYBRIQUE was evaluated in a randomized, double-blind, placebo-controlled, flexible-dose study of 475 adult men with ED. Over the 12-week study, participants received VYBRIQUE at doses of 25 mg, 50 mg, 75 mg and 100 mg. The study's co-primary efficacy endpoints,

assessed at Week 4, demonstrated that VYBRIQUE provided superior improvements in sexual function compared to placebo. Additionally, pharmacokinetic analyses showed that peak plasma concentrations were reached between 30 and 300 minutes (median 80 minutes) under fasting conditions.

“Beyond age-related factors, research[2] shows that anxiety, depression, and stress can contribute to ED,” said Dr. Ralph Zagha, MD, Principal Investigator, Precision Clinical Research. “Providing a treatment option that is discreet and easy to administer supports men in managing ED in a way that feels approachable and respectful of their sexual health.”

IBSA USA is committed to supporting the millions of men affected by ED through filling the treatment gap. For more information on VYBRIQUE, click here.

About VYBRIQUE™
VYBRIQUE (sildenafil) is the first and only FDA-approved oral film for the treatment of erectile dysfunction in adult men in the US.

What is VYBRIQUE?
VYBRIQUE (sildenafil) oral film is a prescription medicine used to treat erectile dysfunction (ED). VYBRIQUE is not for use in women or children. It is not known if VYBRIQUE is safe and effective in women or children under 18 years of age.

IMPORTANT SAFETY INFORMATION

VYBRIQUE can cause your blood pressure to drop suddenly to an unsafe level if it is taken with certain other medicines. Do not take VYBRIQUE if you take medicines called nitrates. A sudden drop in blood pressure can cause you to feel dizzy, faint, or have a heart attack or stroke.

Do not take VYBRIQUE if you take medicines called guanylate cyclase stimulators, which include riociguat, a medicine that treats pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. Do not take VYBRIQUE if you are allergic to sildenafil or any of the ingredients in VYBRIQUE.

Tell all your healthcare providers that you take VYBRIQUE. If you need emergency medical care for a heart problem, it will be important for your healthcare provider to know when you last took VYBRIQUE.

Stop sexual activity and get medical help right away if you get symptoms such as chest pain, dizziness, or nausea during sex. Sexual activity can put an extra strain on your heart, especially if your heart is already weak from a heart attack or heart disease. VYBRIQUE does not protect you or your partner from getting sexually transmitted diseases, including Human Immunodeficiency Virus (HIV).

VYBRIQUE can cause serious side effects including:
• **an erection that will not go away (priapism).** If you have an erection that lasts more than 4 hours, get medical help right away because priapism can permanently damage your penis.

• **sudden vision loss in one or both eyes.** Sudden vision loss in one or both eyes can be a sign of a serious eye problem called non-arteritic anterior ischemic optic neuropathy (NAION). Stop taking VYBRIQUE and call your healthcare provider right away if you have sudden vision loss in one or both eyes.
• **sudden hearing decrease or hearing loss.** Some people may also have ringing in their ears (tinnitus) or dizziness. If you have these symptoms, stop taking VYBRIQUE and contact a healthcare provider right away.

Before you take VYBRIQUE, tell your healthcare provider if you:

- have or have had heart problems such as a heart attack, irregular heartbeat, angina, chest pain, narrowing of the aortic valve or heart failure
- have had heart surgery within the last 6 months
- have pulmonary hypertension
- have had a stroke
- have low blood pressure, or high blood pressure that is not controlled
- have a deformed penis shape
- have had an erection that lasted for more than 4 hours
- have problems with your blood cells such as sickle cell anemia, multiple myeloma, or leukemia
- have retinitis pigmentosa, a rare genetic (runs in families) eye disease
- have ever had severe vision loss, including NAION
- have bleeding problems
- have or have had stomach ulcers
- have liver problems
- have kidney problems or are having kidney dialysis

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your doctor especially if you take any of the following:

- nitrates
- guanylate cyclase stimulators, such as riociguat
- alpha-blockers, such as doxazosin. The use with VYBRIQUE can lead to a drop in blood pressure or to fainting.
- HIV protease inhibitors, such as ritonavir and saquinavir
- oral antifungal medicines, such as ketoconazole and itraconazole
- antibiotics, such as erythromycin
- medicines that treat high blood pressure
- other medicines or treatments for ED

The most common side effects of VYBRIQUE are: headache; flushing; upset stomach; stuffy or runny nose; and dizziness. Other side effects include: abnormal vision, such as changes in color vision and blurred vision; back pain; muscle pain; nausea; and rash.

These are not all of the possible side effects of VYBRIQUE. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088, or contact IBSA Pharma Inc. at 1-800-587-3513.

Please see accompanying Full Prescribing Information and Patient Information.

For further information:
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About IBSA
IBSA (*Institut Biochimique SA*) is a Swiss pharmaceutical multinational with 20 subsidiaries across Europe, China, and the United States. Its products are available in over 90 countries, and its R&D activities focus on 10 therapeutic areas. In 2025, IBSA celebrated the 40th anniversary of its acquisition by current President and CEO, Arturo Licenziati, who has transformed the company into a multinational corporation employing over 2,300 personnel worldwide. IBSA's growth and development can be attributed to its ability to innovate by refining well-known molecules, as well as to its commitment to looking to the future responsibly and transparently, thanks to the dedication and dynamism of its people.

References
[1] Safa A, Waked C. Erectile Dysfunction in Young Adults: A Narrative Review. Cureus. 2025 Aug 12;17(8):e89918. doi: 10.7759/cureus.89918. PMID: 40809937; PMCID: PMC12349891.

[2] National Institute of Diabetes and Digestive and Kidney Diseases. (2024, *Last Reviewed October 2024*). *Symptoms & Causes of Erectile Dysfunction*. U.S. Department of Health and Human Services, National Institutes of Health. Retrieved from https://www.niddk.nih.gov/health-information/urologic-diseases/erectile-dysfunction/symptoms-causes

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