ASSERT Topline Data Results

ASSERT: Phase 3 study evaluating the safety and efficacy of Bylvay® (odevixibat) in patients with Alagille syndrome

October 2022

(Nasdaq: ALBO)

Albireo

For Media & Investors Only

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Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to: whether the regulatory filings to be made for Bylvay in patients with ALGS will be made on the timelines we expect and be approved by the FDA and EMA; whether the FDA and EMA will complete their respective reviews within target timelines, once determined; whether the FDA and EMA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA and EMA request, and whether such additional information will be satisfactory to the FDA and EMA; there are no guarantees that Bylvay will be commercially successful; we may encounter issues, delays or other challenges in commercializing Bylvay; whether Bylvay receives adequate reimbursement from third-party payors; the degree to which Bylvay receives acceptance from patients and physicians for its approved indication; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; challenges associated with supply and distribution activities, which in each case could limit our sales and the availability of our product; results achieved in Bylvay in the treatment of patients with PFIC or other approved indications may be different than observed in clinical trials, and may vary among patients; potential negative impacts of the COVID-19 pandemic, including on manufacturing, supply, conduct or initiation of clinical trials, or other aspects of our business; whether favorable findings from clinical trials of Bylvay to date, including findings in PFIC, ALGS and other indications, will be predictive of results from other clinical trials of Bylvay; there is no guarantee that Bylvay will be approved in jurisdictions or for indications beyond the jurisdictions in which or indications for which Bylvay is currently approved; there is no guarantee that our other products candidates will be approved; estimates of the addressable patient population for target indications may prove to be incorrect; the outcome and interpretation by regulatory authorities of the ongoing third-party study pooling and analyzing of long-term PFIC patient data; the timing for initiation or completion of, or for availability of data from, clinical trials of Bylvay, including BOLD, and the Phase 2 clinical trial of A3907, and the outcomes of such trials; Albireo’s ability to obtain coverage, pricing or reimbursement for approved products in the United States or Europe; delays or other challenges in the recruitment of patients for, or the conduct of, the Company’s clinical trials; any repurchase by the Company of Sagard’s interest in the royalty interest payments under our royalty monetization agreement with Sagard could materially impact our financial condition; and the Company’s critical accounting policies. 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On the Call Today

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Chief Financial Officer

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Chief Commercial Officer

ASSERT

POSITIVE TOPLINE DATA RESULTS

Bylvay® (odevixibat) in Alagille Syndrome Patients

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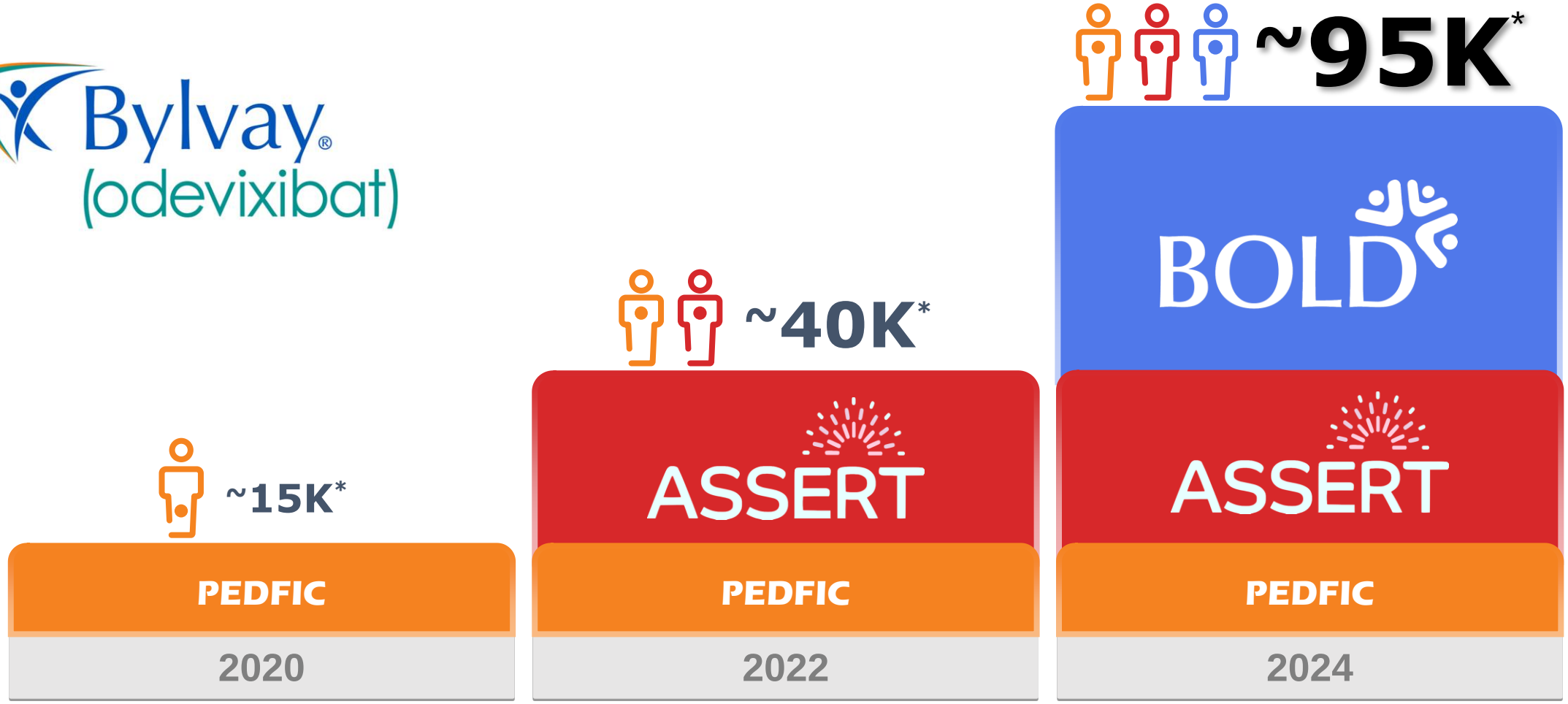
Significant Cholestatic Liver Disease Opportunity

Three Bylvay Phase 3 Gold Standard Studies

Bylvay® (odevixibat)



*Worldwide Prevalence: Top 25 Markets excluding China and India

Alagille Syndrome is a Devastating Disease

Alagille Syndrome (ALGS)

A rare, life-threatening, genetic disorder, with multi-system involvement including paucity of liver bile ducts, leading to bile acid buildup.

- May present in the first **3 months** of life
- **Cholestasis** is the most common feature, typically presenting with unremitting pruritus
- Causes **quality of life impairments** including growth failure, sleep disturbances, disfiguring xanthomas
- Children with ALGS may need a **liver transplant**

ASSERT: Global Phase 3 Pivotal Study

ASSERT: Alagille **S**yndrome **S**afety & **E**fficacy **R**andomized **T**rial

ASSERT OLE

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52 Subjects
Oral capsule/sprinkle
Once daily

Key Inclusion Criteria:

- Patient of any age with genetically confirmed diagnosis of ALGS
- History of significant pruritus
- Elevated sBA level

24-Week Treatment
2:1 Randomization

R

Odevixibat
120 µg/kg/day
N=35

Placebo
N=17

A Phase 3 Double-blind, Randomized, Placebo-controlled Study of the Safety and Efficacy of Odevixibat in Patients with ALGS

Primary Endpoint

Change from baseline in scratching to month 6 (weeks 21 to 24) as measured by the Albireo ObsRO caregiver instrument

Optional Enrollment
Open Label Extension

Safety Follow-up

32 global sites

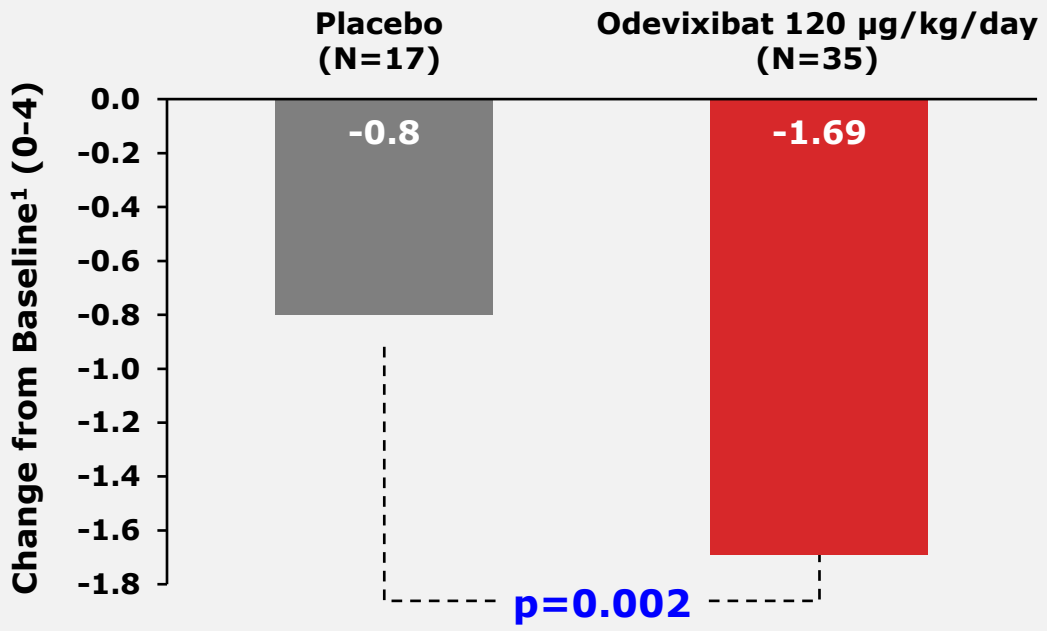
Key Baseline Demographics & Characteristics

	Placebo N=17	Odevixibat N=35
Age (years); mean (SD)	**5.40** (4.411)	**6.73** (3.780)
Sex (% female)	**64.7**	**40.0**
Serum bile acids (µmol/L); mean (SD)	**246.1** (120.53)	**237.4** (114.88)
Pruritus (0-4 scale); mean (SD)	**3.01** (0.636)	**2.80** (0.520)
Use of anti-pruritus medication; n (%)	**17** (100.0)	**34** (97.1)
ALT (U/L); mean (SD)	**149.1** (84.15)	**185.6** (83.20)
Total bilirubin (µmol/dL); mean (SD)	**61.62** (57.022)	**51.99** (43.380)

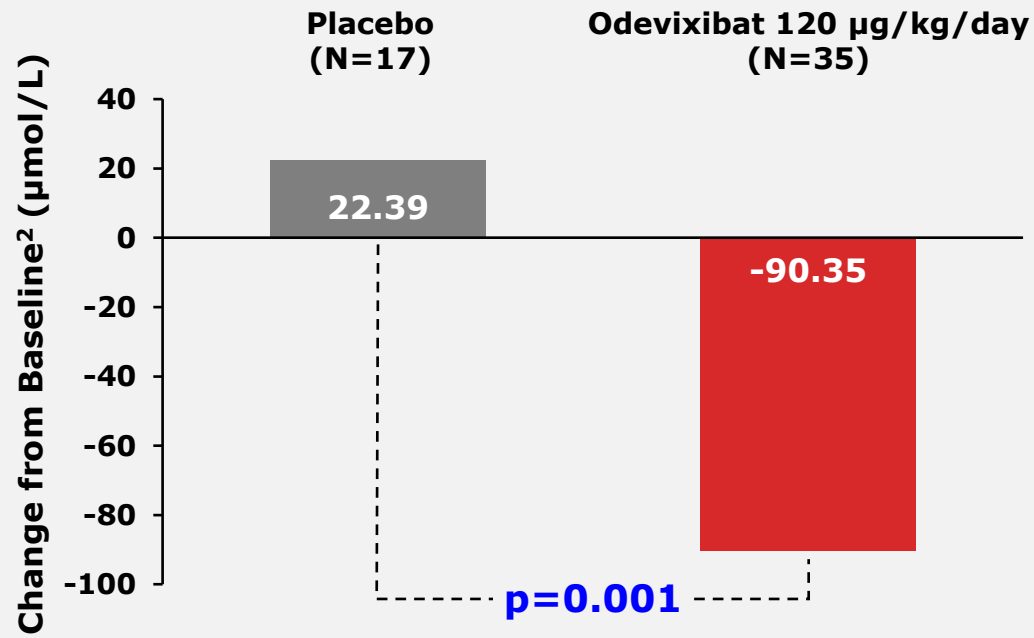
No discontinuations, all 52 patients completed the 24-week treatment period.

Highly Statistically Significant Change in Pruritus and Serum Bile Acids

Primary: Pruritus



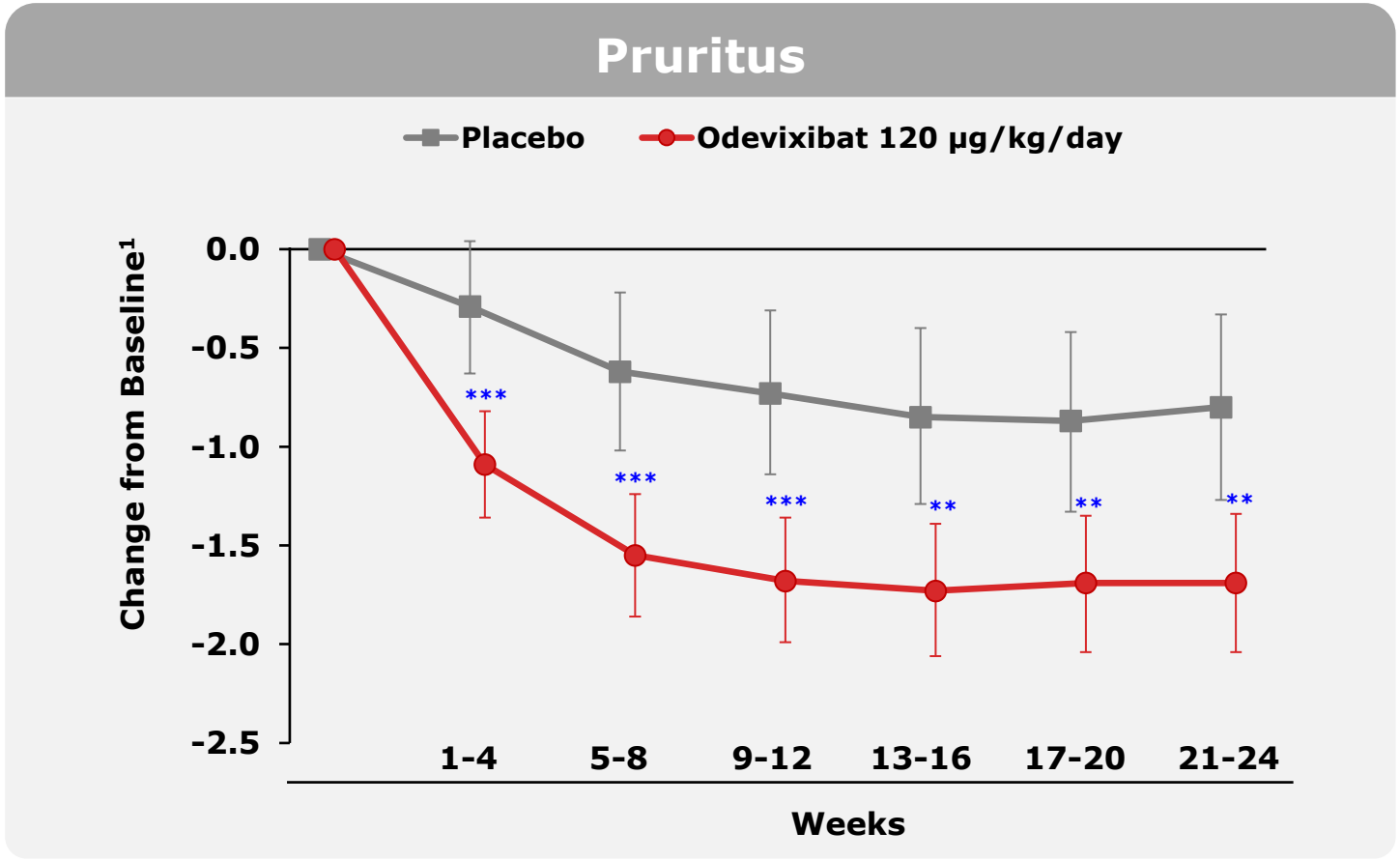
Key Secondary: Serum Bile Acids



24-week treatment with Bylvay led to highly statistically significant improvement in pruritus severity and reduction in serum bile acid levels compared to placebo

1. LS Mean at weeks 21-24
2. LS Mean at weeks 20 and 24

Early, Rapid, Sustained Pruritus Improvements



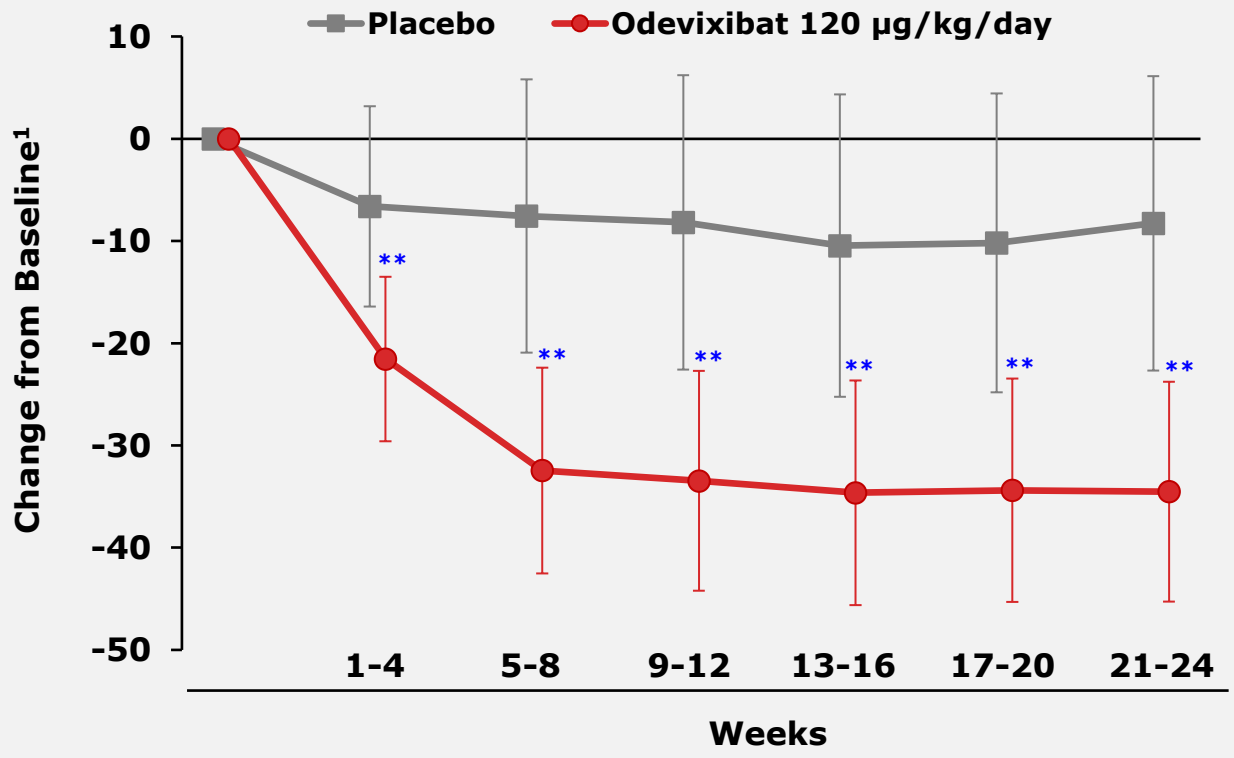
*p≤0.05
**p≤0.01
***p≤0.001

At all time points, early, rapid and sustained, highly statistically significant improvement in scratching score with Bylvay compared to placebo.

1. LS Mean (95% CI)

Profound Sleep Improvements Over Time[1]

Days Sleeping with Caregiver (%)



*p≤0.05
**p≤0.01
***p≤0.001

At all time points, Bylvay treatment led to fewer days sleeping with a caregiver

1. Secondary Endpoint
2. LS Mean (95% CI)

Substantial Improvement in Multiple Sleep Parameters

- Days with help falling asleep (p=0.003)
- Days with soothing (p<0.0001)
- Days sleeping with caregiver (p=0.003)
- Tiredness (PM) (p=0.012)

Sleep deprivation and disruption can have profound impact on caregiver and patient quality of life

Well Tolerated with a Low Incidence of Diarrhea

		Placebo N=17 n (%)	Odevixibat N=35 n (%)
Adverse events		**12** (70.6)	**26** (74.3)
Serious adverse events		**2** (11.8)	**5** (14.3)
Drug Related TEAEs in ≥5%*	Diarrhea	**1** (5.9)	**4** (11.4)
	Vomiting	**0**	**2** (5.7)
Deaths (safety analysis)		**0**	**0**
Discontinuations due to AE		**0**	**0**

Bylvay was well tolerated over 24 weeks, no discontinuations

*≥5% in odevixibat group

Bylvay ASSERT Phase 3 Results Summary

FIRST, ONLY & LARGEST PHASE 3 STUDY IN ALAGILLE SYNDROME
Randomized, placebo-controlled

DIVERSE, GLOBAL STUDY POPULATION
Trial enrolled patients from birth to young adults with both JAG1 and NOTCH2 mutations

ACHIEVED HIGHLY STATISTICAL SIGNIFICANCE
Pruritus, serum bile acids, sleep efficacy endpoints

WELL TOLERATED, NO DISCONTINUATIONS
Low drug-related diarrhea rate, almost all patients rolled over to extension study

Robust topline data to support regulatory filings – plans to complete in Q1 2023

Nadia Ovchinsky, MD, MBA, FAALSD

Principal Investigator, ASSERT Study

Nadia Ovchinsky, MD, MBA, FAALSD

Director of Pediatric Hepatology

Medical Director of Pediatric Liver Transplantation, Children's Hospital at Montefiore

Professor of Pediatrics, Albert Einstein College of Medicine

Gold Standard Phase 3 Studies

ASSERT

1st IBATi Phase 3 ALGS Study

Pruritus endpoint (p=0.002)

Bile acids endpoint (p=0.001)

Diarrhea vs placebo (11.4% vs 5.9%)

PEDFIC

1st IBATi Phase 3 PFIC Study

Pruritus endpoint (p=0.004)

Bile acids endpoint (p=0.003)

Diarrhea vs placebo (9.5% vs 5.0%)

Compelling evidence for regulators, payers and prescribers

Bylvay Plans and Priorities

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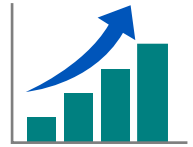
US and Europe Regulatory Filings Q1 2023

BOLD

Biliary Atresia Phase 3 Study Full Enrollment Q4 2022

Bylvay® (odevixibat)



Generate PFIC Sales Launch in Additional EU Countries

Strong financial foundation with over $270 million of cash

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