For cholestatic pruritus in your patients with Alagille syndrome (ALGS)

Grow up with BYLVAY®*

with flexible administration options[1]

RAPID REDUCTION IN CHOLESTATIC PRURITUS AS EARLY AS WEEKS 1-4[1-3]

ASSERT primary endpoint:
Change from baseline in average scratching score to Month 6 (−1.7 for BYLVAY vs −0.8 for placebo)[1,3]

The means (95% confidence interval) of patients' average scratching scores in each treatment group for each month with reductions as early as Weeks 1-4 was assessed in ASSERT.[1]

All images are actor portrayals.

*BYLVAY can be taken 3 ways: swallow capsules whole; open capsules or oral pellets and mix contents with soft food or liquid.[1]

INDICATION

BYLVAY (odevixibat) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients ≥12 months of age with Alagille syndrome (ALGS).

IMPORTANT SAFETY INFORMATION

Contraindications

IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

WARNINGS AND PRECAUTIONS

Hepatotoxicity

BYLVAY treatment is associated with a potential for drug-induced liver injury (DILI).

Bylvay® (odevixibat)
200 | 400 | 600 | 1200 mcg capsules

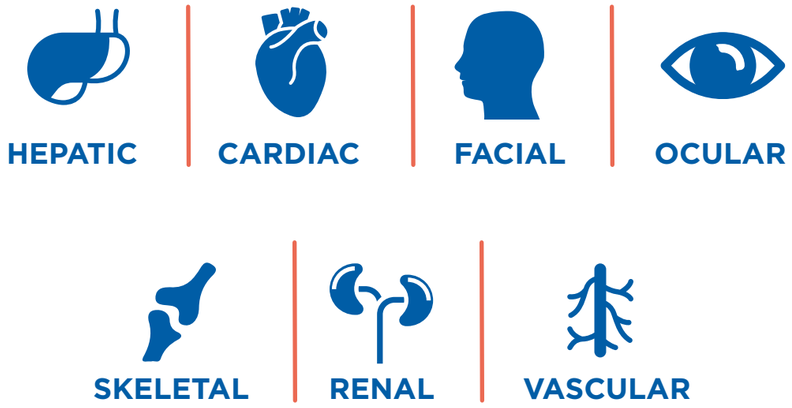
Please see additional Important Safety Information throughout and the full Prescribing Information.

Recognizing and diagnosing ALGS early is critical[4,5]

ALGS can be diagnosed clinically or in combination with genetic testing[6-8]

Meeting 3 of 7 clinical criteria can establish a diagnosis[6]

Clinical diagnosis is based on involvement of at least 3 of the 7 main organ systems affected[6]:



A pathogenic variant in *JAG1* or *NOTCH2* can establish a diagnosis[8]

Molecular diagnosis can be established in patients with a heterozygous pathogenic or likely pathogenic finding in the *JAG1* (94% of cases) or *NOTCH2* (2-4% of cases) genes through genetic testing[7,8]

Early diagnosis of ALGS may improve patient management[4,5]

Cholestatic pruritus can be one of the most bothersome symptoms and may be caused by impaired bile flow[9,10]

Please see additional Important Safety Information throughout and the full Prescribing Information.

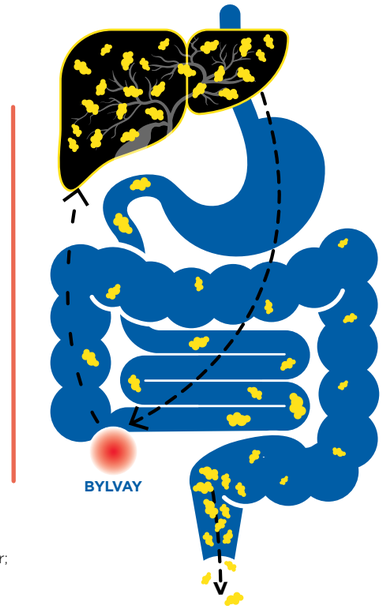
BYLVAY decreases reabsorption of bile acids[1]

ALGS is characterized by impaired enterohepatic circulation[9]

- ALGS causes bile duct paucity, which results in cholestasis[9,11]
- Disruption to normal bile flow leads to bile acid accumulation in the liver[9,12,13]
- Excess bile acid "spills over" into the bloodstream, elevating serum bile acid (sBA) levels.[9] Elevated sBA may play a role in pruritus[14,15]
- The ileal bile acid transporter (IBAT) helps regulate the bile acid (BA) pool, reabsorbing up to 95% of secreted BA[9]

BYLVAY reversibly inhibits the ileal bile acid transporter (IBAT)[1]

1. **Reversibly inhibits the IBAT, decreasing bile acid reabsorption in the terminal ileum[1,9]**
2. **Decreasing reabsorption in the terminal ileum increases excretion[1,9]**
3. **Decreased reabsorption is observed as a decrease in serum bile acid levels[1,9]**
4. **The mechanism by which BYLVAY improves pruritus is not fully understood[1]**



ALGS=Alagille syndrome; IBAT=ileal bile acid transporter; sBA=serum bile acid.

BYLVAY was minimally absorbed and no accumulation was observed following once-daily dosing[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Hepatotoxicity (cont'd)

In the ALGS trials, treatment-emergent elevations or worsening of liver tests occurred. Of the three patients who experienced DILI during the ALGS trials, one patient permanently discontinued treatment.

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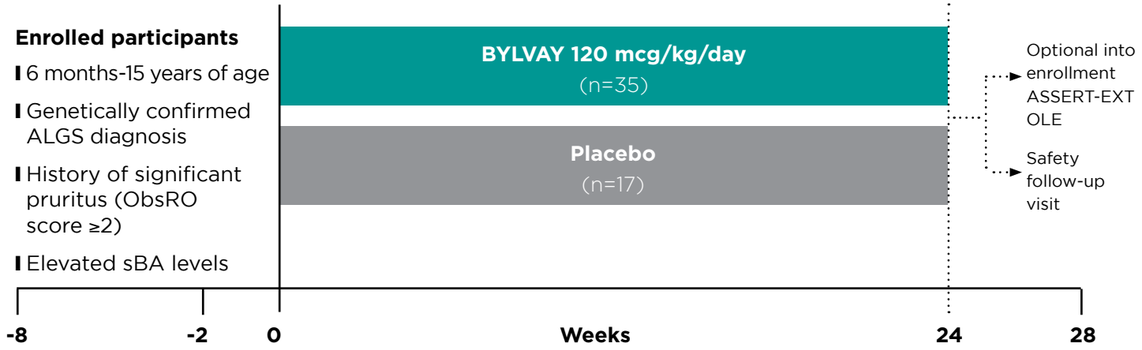
ASSERT is the FIRST and ONLY randomized Phase 3 trial of an IBAT inhibitor in ALGS[3,16]

ASSERT[1,3]

24-week randomized, double-blind Phase 3 study

All BYLVAY doses were administered once daily



Primary Endpoint:

- Change from baseline in average scratching score to Month 6 (Weeks 21 to 24)

Secondary Endpoints included:

- Change from baseline in sBA levels through Week 24
- Proportion of participants achieving a clinically meaningful decrease in pruritus
- Change from baseline in sleep parameters through Week 24*

The only pivotal trial of an IBATi to enroll participants with *JAG1* (92%) and *NOTCH2* (8%) variants.[1,17]

Concomitant ursodeoxycholic acid (UDCA) and other antipruritic medications were permitted provided they were at a stable dose at least 4 weeks before enrollment with no dosage changes planned during the study period.[3]

98% of participants were receiving antipruritic medications and 89% were receiving UDCA at baseline.[18]

*Data reported using the PRUCISION™ ObsRO instrument; caregivers answered 9 questions about the effects that itch had on their child's sleep and sleep-related parameters daily.[3,18]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Hepatotoxicity (cont'd)

Obtain baseline liver tests because some ALGS patients have abnormal liver tests at baseline and monitor patients frequently for the first 6 to 8 months, and as clinically needed thereafter, for elevations in liver tests, for the development of liver-related adverse reactions, and for physical signs of hepatic decompensation. If liver test abnormalities or signs of clinical hepatitis occur in the absence of other causes, consider dose reduction or treatment interruption. Permanently discontinue BYLVAY if a patient experiences the following: persistent or recurrent liver test abnormalities, or upon rechallenge, signs and symptoms consistent with clinical hepatitis, or a hepatic decompensation event.

Cholestatic pruritus was measured using the PRUCISION™ ObsRO scale[1,3]

PRUCISION™ ObsRO Scale

A **validated** instrument that defines a ≥1-point reduction as a clinically meaningful change in pruritus score.[19]

Caregivers recorded scratching scores twice daily based on the following questions[18,19]:

- AM score: How bad was your child's worst scratching since he/she went to bed last night?
- PM score: How bad was your child's worst scratching since he/she woke up this morning?

IBATi=ileal bile acid transporter inhibitor; ObsRO=observer-reported outcomes; OLE=open-label extension.

Please see additional Important Safety Information throughout and the full Prescribing Information.

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ASSERT

Rapid and durable reduction in cholestatic pruritus as early as Weeks 1-4[2]

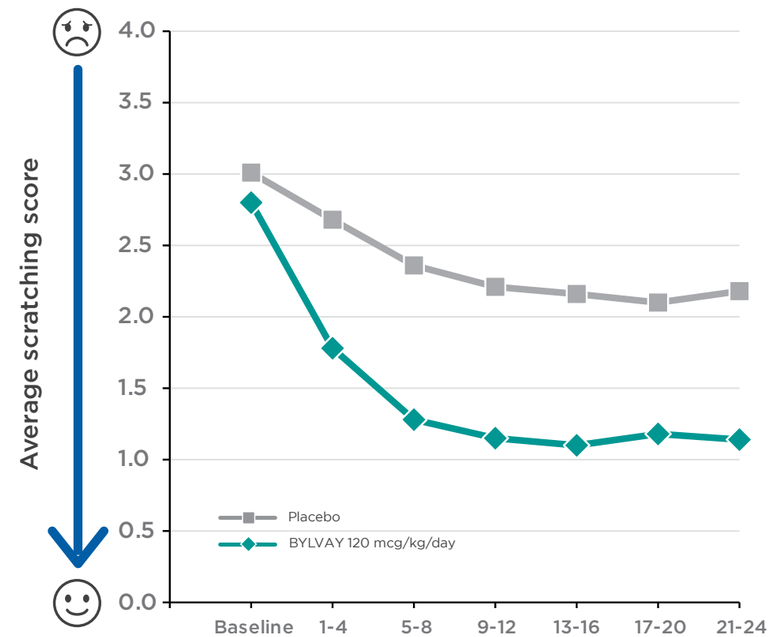
ASSERT

Pruritus reduction data at Weeks 1-4[20]

Significant reductions in pruritus

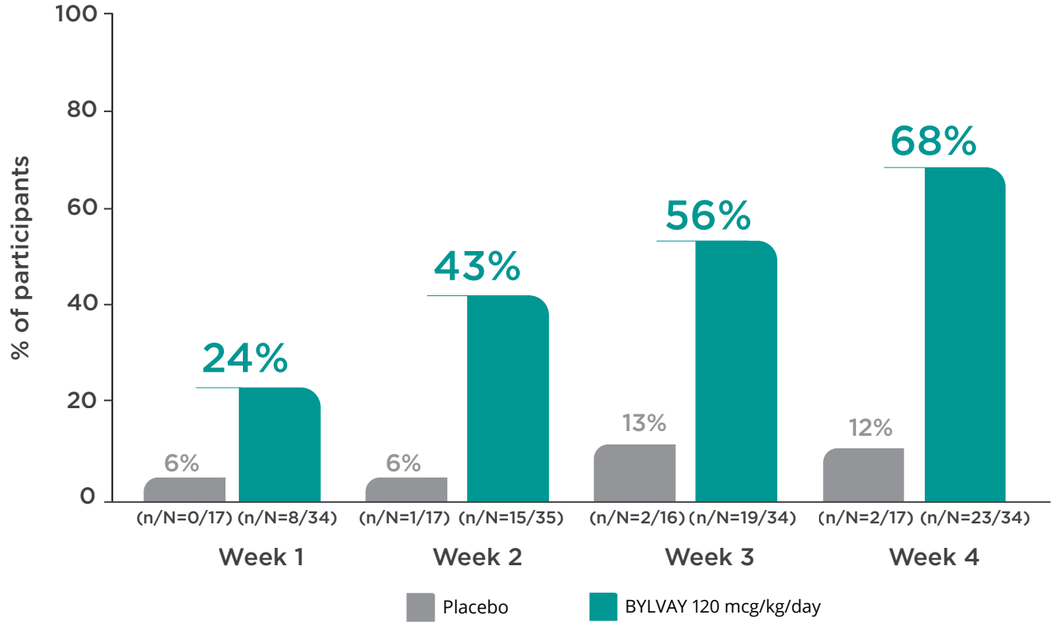
ASSERT Primary Endpoint: Change from baseline in average scratching score to Month 6 (Weeks 21-24): -1.7 for BYLVAY vs -0.8 for placebo (*P*=0.002)[1]

ASSERT: Average scratching score through Week 24[2]



Participants, n							
Placebo → BYLVAY	17	17	17	16	15	17	16
All BYLVAY → BYLVAY	35	34	34	34	34	35	34

Proportion of participants experiencing a clinically meaningful* reduction in average scratching score at Weeks 1 to 4[20]



LIMITATION: Week 1-4 clinically meaningful improvement data are descriptive and not powered to determine statistical significance; interpret with caution.

Clinically meaningful improvements in pruritus through 24 weeks

80% **of participants** treated with BYLVAY experienced a clinically meaningful reduction in pruritus at **Week 24** (35% with placebo)[21]

up to **91%** **of participants** treated with BYLVAY achieved a clinically meaningful reduction in pruritus at any time throughout the ASSERT trial[22]

*Defined as a ≥1-point reduction in ObsRO score.

ObsRO=observer-reported outcomes.

IMPORTANT SAFETY INFORMATION (CONT'D)

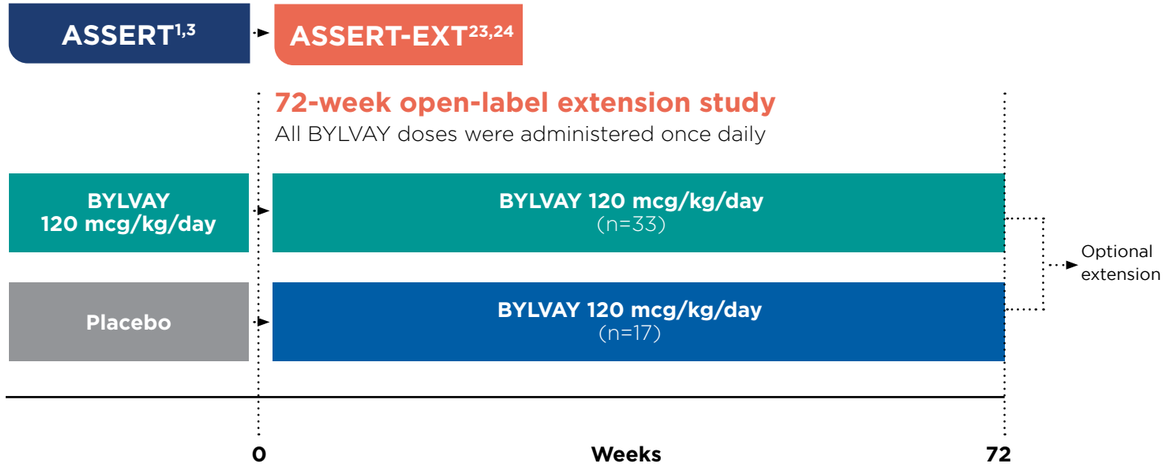
WARNINGS AND PRECAUTIONS

Hepatotoxicity (cont'd)

The safety and effectiveness of BYLVAY have not been established in patients with decompensated cirrhosis. Monitor patients with compensated cirrhosis or portal hypertension more frequently and discontinue if hepatic decompensation occurs. IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events.

Please see additional Important Safety Information throughout and the full Prescribing Information.

ASSERT-EXT is an open-label extension study to assess long-term efficacy and safety[23,24]



Primary Endpoint:

- Change from baseline in average scratching score through Week 72

Secondary Endpoints included:

- Change from baseline in sBA at Week 72
- Change from baseline in sleep parameters through Week 72*

*Data reported using the PRUCISION™ ObsRO instrument; caregivers answered 9 questions about the effects that itch had on their child's sleep and sleep-related parameters daily.[3,25]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

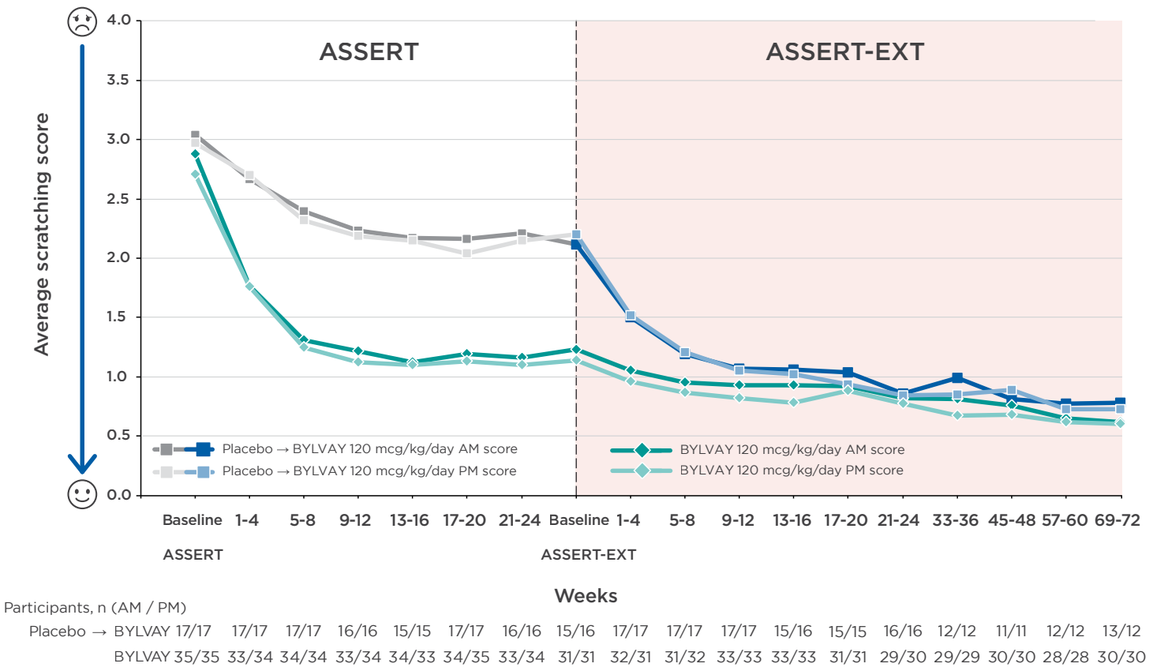
Diarrhea

In the ALGS clinical trials, diarrhea was reported more frequently in BYLVAY-treated patients compared to placebo. In the ALGS clinical trials, no patients interrupted or discontinued treatment due to diarrhea.

If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt dosing if a patient experiences persistent diarrhea. Restart BYLVAY at 40 mcg/kg/day when diarrhea resolves and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop treatment.

Impact of once-daily BYLVAY on pruritus throughout the day and night[26]

Average day and night scratching scores through Week 96[26]*



Participants, n (AM / PM)																		
Placebo → BYLVAY	17/17	17/17	17/17	16/16	15/15	17/17	16/16	15/16	17/17	17/17	17/17	15/16	15/15	16/16	12/12	11/11	12/12	13/12
BYLVAY	35/35	33/34	34/34	33/34	34/33	34/35	33/34	31/31	32/31	31/32	33/33	33/33	31/31	29/30	29/29	30/30	28/28	30/30

LIMITATION: Data are descriptive and not powered to determine statistical significance; interpret with caution.

Reductions were observed through 96 weeks[26]

ASSERT-EXT is an open-label extension of the ASSERT trial.[24]

*AM score reflects nighttime scratching; PM score reflects daytime scratching.[18,25]

Please see additional Important Safety Information throughout and the full Prescribing Information.

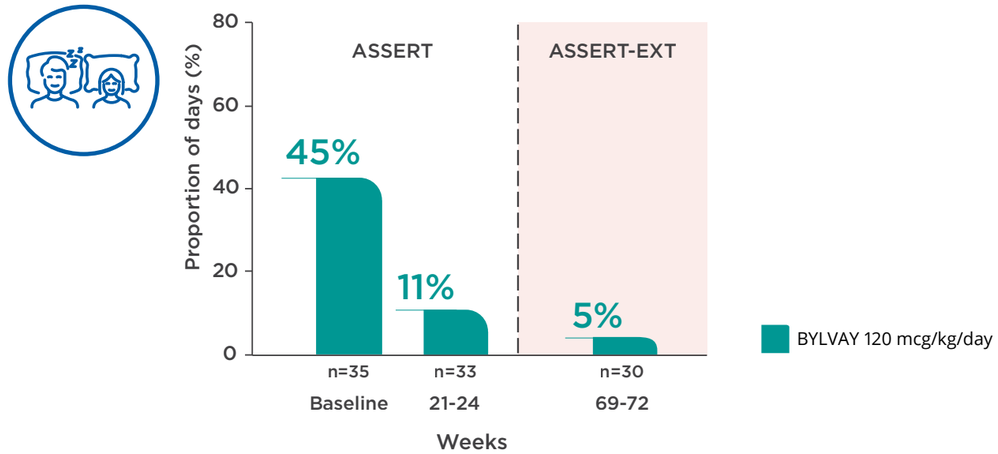
Bylvay® (odevixibat) 200 | 400 | 600 | 1200 mcg capsules

Long-term BYLVAY data on itch-related sleep disruptions

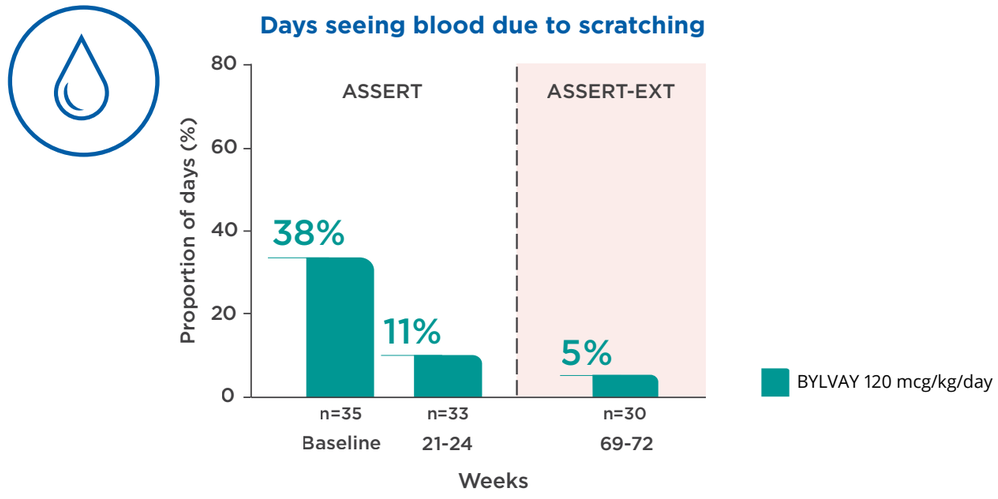
Data on reduction in pruritus-associated sleep disruption at 96 weeks[27]

24 weeks in ASSERT (N=35) and 72 weeks in ASSERT-EXT (N=33)

Days needing to sleep with a caregiver



Days seeing blood due to scratching

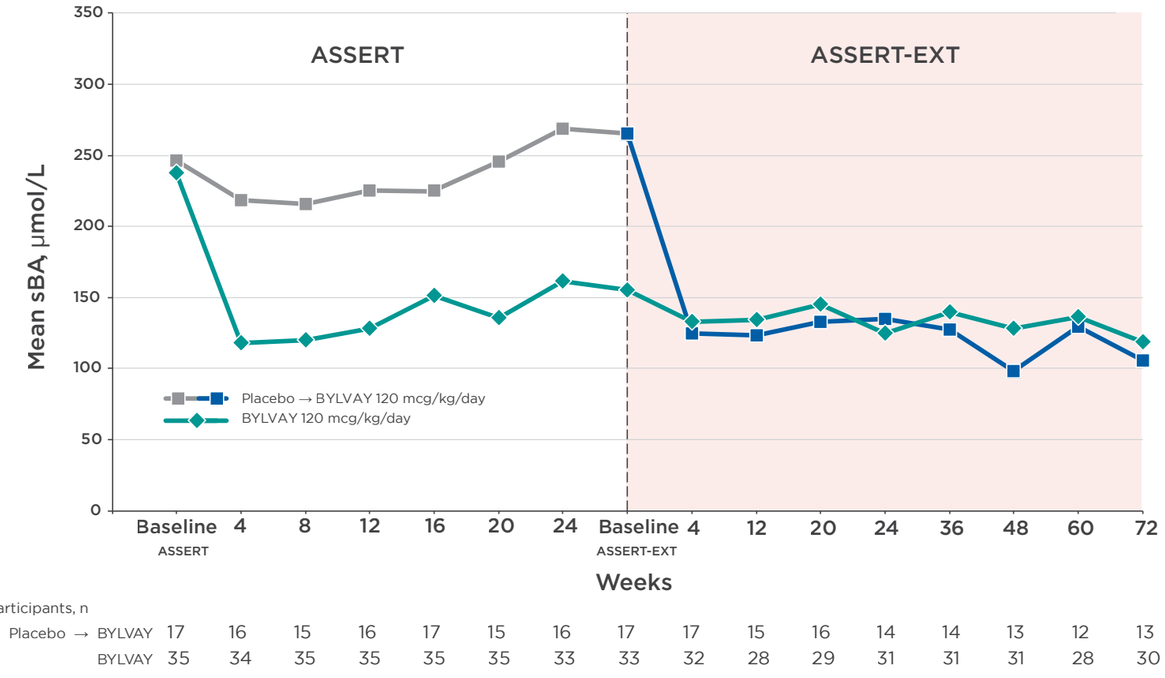


LIMITATION: Data are descriptive and not powered to determine statistical significance; interpret with caution.

Data on reduction in serum bile acids at 96 weeks

RAPID sBA REDUCTION

Mean sBA levels through Week 96[2,23,28]



Participants, n																
Placebo → BYLVAY	17	16	15	16	17	15	16	17	17	15	16	14	14	13	12	13
BYLVAY	35	34	35	35	35	35	33	33	32	28	29	31	31	31	28	30

LIMITATIONS: The clinical trial was not designed to make conclusions regarding the clinical benefit of sBA reduction. The correlation between sBA and clinical outcomes is not known. sBA levels do not accurately predict bile acids in the liver. It is unknown whether the sBA assay was qualified to assess sBA levels during the analysis.

ASSERT-EXT is an open-label extension of the ASSERT trial.[24]

Please see additional Important Safety Information throughout and the full Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Fat-Soluble Vitamin (FSV) Deficiency

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K. ALGS patients can have FSV deficiency at baseline. BYLVAY may adversely affect absorption of FSVs. In clinical trials, new onset or worsening of existing FSV deficiency was reported more frequently in BYLVAY-treated patients compared to placebo.

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Through Week 24

Safety profile established in ASSERT[3]

Rates of Serious Adverse Events (SAEs)[3]

Participants with any	Placebo (n=17) n (%)	BYLVAY 120 mcg/kg/day (n=35) n (%)
Treatment-emergent SAEs	2 (12)	5 (14)
Drug-related treatment-emergent SAEs	0	1 (3)

- Drug-related treatment-emergent SAEs in the BYLVAY group included hematemesis and increased INR[3]
- There were no discontinuations[3]
- No deaths were reported[3]
- Rates of fat-soluble vitamin deficiency were[29]:
  — 8.6% with BYLVAY 120 mcg/kg/day (n=35)
  — 17.6% with placebo (n=17)

Common Adverse Reactions (≥5%)[1]

Adverse reaction	Placebo (n=17) n (%)	BYLVAY 120 mcg/kg/day (n=35) n (%)
Diarrhea	1 (6)	10 (29)
Abdominal pain	1 (6)	5 (14)
Hematoma	0	3 (9)
Weight decreased	0	2 (6)

- Most treatment-emergent adverse events (TEAEs) were mild to moderate in severity[3]
- All reports of diarrhea were grade 1 intensity (mild)[3]
- Treatment-related clinically significant diarrhea was reported in[29]:
  — 1 participant receiving BYLVAY (duration: 4 days)
  — 1 participant receiving placebo (duration: 24 days)

Please see additional Important Safety Information throughout and the full Prescribing Information.

Through Week 72

Long-term safety profile established in ASSERT-EXT

Rates of SAEs[30]

Participants with any	Placebo*→BYLVAY 120 mcg/kg/day (n=17) n (%)	BYLVAY*→BYLVAY 120 mcg/kg/day (n=33) n (%)
Treatment-emergent SAEs	7 (41)	4 (12)
Drug-related treatment-emergent SAEs	0	0

Eleven (22.0%) of 50 participants experienced treatment-emergent SAEs, with all assessed as unrelated to BYLVAY. The most common reported type of SAE was infections; this included enterovirus infection, gastroenteritis, rotavirus gastroenteritis, and chronic otitis media. No SAEs led to treatment discontinuation, and no deaths were reported.

Common TEAEs (≥10%)[30]

Adverse reaction	Placebo*→BYLVAY 120 mcg/kg/day (n=17) n (%)	BYLVAY*→BYLVAY 120 mcg/kg/day (n=33) n (%)
Nasopharyngitis	6 (35)	9 (27)
Diarrhea	6 (35)	7 (21)
Bronchitis	0	5 (15)
Cough	2 (12)	5 (15)
Influenza	1 (6)	5 (15)
Otitis media	2 (12)	5 (15)
Pyrexia	4 (24)	5 (15)
COVID-19	4 (24)	4 (12)
Ear infection	2 (12)	4 (12)
Pharyngitis	1 (6)	4 (12)
Upper respiratory tract infection	4 (24)	4 (12)
Rhinitis	2 (12)	3 (9)
Vitamin D deficiency	4 (24)	3 (9)
Vitamin E deficiency	3 (18)	2 (6)
Alanine aminotransferase increased	2 (12)	1 (3)
Otitis media acute	2 (12)	1 (3)
Rhinorrhea	3 (18)	1 (3)
Viral infection	3 (18)	1 (3)
INR increased	3 (18)	0

Additional TEAEs reported in ≥5% of participants in either cohort included conjunctivitis, eczema, pruritus, tonsilitis, viral upper respiratory tract infection, vitamin K deficiency, abdominal pain, headache, and lymphadenopathy.

ASSERT-EXT is an open-label extension of the ASSERT trial.[24]

*Treatment group in ASSERT.

INR=international normalized ratio.

BYLVAY offers once-daily dosing and flexible administration[1]

The **ONLY IBAT inhibitor** that:

✔ **CAN BE** mixed with soft food or age-appropriate liquid[31]

✔ **DOES NOT** require fasting or delaying of meals[31]

✔ **DOES NOT** require dose titration for standard treatment initiation[31]

1 **daily dose** taken with a morning meal[1]

2 **oral formulation options:** oral pellets, capsules[1]

3 **ways to take:** swallow capsules whole; mix contents* with soft food or liquid[1]

*Pellets or capsules.

Oral Pellets[1]

For patients weighing <19.5 kg

Capsules[1]

For patients weighing ≥19.5 kg

Do not crush or chew capsules

After mixing BYLVAY with food or liquids, discard the empty shells.[1]

†Add 1 teaspoon (5 mL of liquid) of an age-appropriate liquid (for example, breast milk, infant formula, or water).

Dosing for cholestatic pruritus in ALGS[1]

- Recommended dose: **120 mcg/kg/day**
- Dose reduction to 40 mcg/kg/day may be considered if tolerability issues occur in the absence of other causes. Once tolerability issues stabilize, increase to 120 mcg/kg/day

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Fat-Soluble Vitamin (FSV) Deficiency (cont'd)

Obtain baseline INR (International Normalized Ratio) and FSV levels and monitor during treatment along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue BYLVAY if FSV deficiency persists, worsens, or complications occur despite adequate FSV supplementation.

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Indication and Important Safety Information

INDICATION

BYLVAY is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients ≥12 months of age with Alagille syndrome (ALGS).

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Diarrhea

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If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt dosing if a patient experiences persistent diarrhea. Restart BYLVAY at 40 mcg/kg/day when diarrhea resolves and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop treatment.

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Obtain baseline INR (International Normalized Ratio) and FSV levels and monitor during treatment along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue BYLVAY if FSV deficiency persists, worsens, or complications occur despite adequate FSV supplementation.

If bone fracture occurs, consider interrupting BYLVAY treatment and supplement with FSV if indicated.

If bleeding occurs, interrupt treatment with BYLVAY. Optimize treatment of FSV deficiency and consider restarting BYLVAY once the patient is clinically stable.

Adverse Reactions

The most common adverse reactions for BYLVAY patients with ALGS are diarrhea, abdominal pain, hematoma, and decreased weight.

Drug Interactions

For patients taking bile acid binding resins, take BYLVAY at least 4 hours before or 4 hours after taking a bile acid binding resin.

Use in Specific Populations

Limited human data on BYLVAY use in pregnant persons are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Based on findings from animal reproduction studies, BYLVAY may cause cardiac malformations when a fetus is exposed during pregnancy. As BYLVAY may inhibit the absorption of fat-soluble vitamins, which are essential for normal fetal growth and development, monitor pregnant patients for FSV deficiency and increase supplementation as needed. Consider the woman's need for BYLVAY, the potential drug-related risks to the fetus, and the potential adverse outcomes from untreated maternal ALGS.

There is a pregnancy exposure registry that monitors pregnancy outcomes in persons exposed to BYLVAY during pregnancy. Pregnant women exposed to BYLVAY, or their healthcare providers, should report BYLVAY exposure by calling 1-855-463-5127.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information.

REFERENCES

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Grow up with BYLVAY*

with flexible administration options[1]

RAPID REDUCTION IN CHOLESTATIC PRURITUS AS EARLY AS WEEKS 1-4[1-3]

Rapid and durable reduction in pruritus[2]

Once-daily dosing with flexible administration options[1]

The **ONLY IBAT inhibitor** that:

- ✔ Does not require fasting or delaying of meals[31]
- ✔ Has a randomized Phase 3 trial[3,16]
- ✔ Does not require dose titration for standard treatment initiation[31]

IPSEN CARES® offers coverage, access, reimbursement, and education support for patients prescribed BYLVAY

Scan to learn more

ASSERT primary endpoint:
Change from baseline in average scratching score to Month 6 (−1.7 for BYLVAY vs −0.8 for placebo)[1,3]

The means (95% confidence interval) of patients' average scratching scores in each treatment group for each month with reductions as early as Weeks 1-4 was assessed in ASSERT.[1]

*BYLVAY can be taken 3 ways: swallow capsules whole; open capsules or oral pellets and mix contents with soft food or liquid.[1]

INDICATION

BYLVAY (odevixibat) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients ≥12 months of age with Alagille syndrome (ALGS).

IMPORTANT SAFETY INFORMATION

Contraindications

IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

Please see additional Important Safety Information throughout and the full Prescribing Information.

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