Ironwood Pharmaceuticals

Linaclotide CC Data: Strong As Expected - ALERT

Overweight

IRWD, IRWD US
Price: $12.92

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Biotechnology

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At the Digestive Disease Week (DDW) meeting today, Dr. Anthony Lembo presented phase 3 data from two trials of linaclotide in chronic constipation (CC). The data were presented in a plenary session at the meeting and were in line with expectations; recall that top-line data were available last fall in CC and today there were no meaningful updates. The primary and secondary endpoints all showed consistent efficacy with a clean safety profile. There was a single death in the aggregated phase 3 studies on linaclotide; this patient apparently died from a fentanyl patch overdose, not related to study drug. The most common AE was diarrhea, which accounted for withdrawal in both studies in 4% of patients (placebo: 0.5%) but it is mild to moderate and it is a widely expected AE for a constipation study. Overall, our view and the view of Dr. Ashok Tuteja, a GI KOL we spoke with on our "LIVE from DDW" call today, was that the CC data were strong and support approval with the next major event to round out the linaclotide clinical profile being IBS-C phase 3 data in 4Q. Reiterate Overweight on IRWD shares.

- **Key efficacy endpoints met.** The primary endpoint at the higher dose (266 ug daily) was met in the '303 study (19.4% vs. 3.3%; p<0.0001) and the '01 study (21.3% vs. 6%; p<0.0001). The lower dose (166 ug daily) also yielded robust significance in the two ph 3 CC studies. For secondary endpoints, all were met with robust significance; these included weekly SBM rate, stool consistency, straining severity, bloating, abdominal discomfort, constipation severity and QOL. In addition, linaclotide showed a reversal of the weekly CSBM rate in the 4-week randomized withdraw period, which further supports its efficacy.
- **Safety looks solid:** For the combined '303 and '01 studies, the overall SAE rate was 2% for placebo, 1% for the 133 ug dose and 3% for the 266 ug dose. The discontinuation rate due to AEs was similar (4% vs. 7% at 133 ug and 7% at 266 ug) with diarrhea being the most common. Overall, we were encouraged by the safety profile; the diarrhea potentially has commercial implications but that said, several investigators have cited that it is mild / moderate in nature.
- **KOL CC feedback is strong.** We hosted a "LIVE from DDW" call earlier today with KOL Dr. Ashok Tuteja who is attending the meeting and provided his quick view of the CC data and how linaclotide could fit into the treatment paradigm. Overall, Dr. Tuteja believed that the data were as expected, with the key unknown being the phase 3 IBS-C data in 4Q. For the CC data, Dr. Tuteja was not concerned about the diarrhea seen with linaclotide as it is a natural AE in CC / IBS-C trials and occurred at a rate that was generally consistent with Amitiza's. The overall profile of the CC dataset was seen as consistent and should point to ultimate approval and a place in the CC treatment paradigm.
- **KOL feedback highlights pain importance in IBS-C.** Phase 3 data in IBS-C are expected in 4Q and based on his analysis of the phase 2 data, Dr. Tuteja believes that linaclotide is likely to show a benefit on pain. This would be very differentiated given a dual label and a benefit on pain, which is an AE widely seen in IBS-C. Overall, we think that linaclotide is setting up for a broad and consistent dataset that is commercially attractive.

See page 2 for analyst certification and important disclosures, including non-US analyst disclosures.

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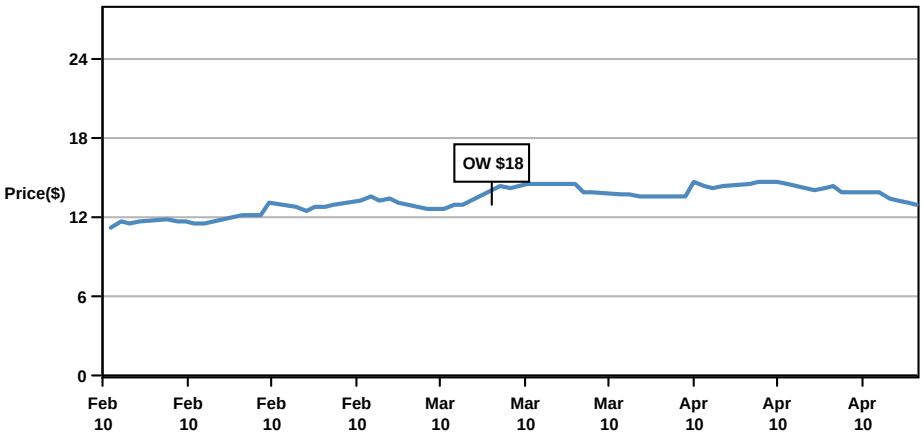
Ironwood Pharmaceuticals (IRWD) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
15-Mar-10	OW	12.91	18.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Mar 15, 2010. This chart shows J.P. Morgan's continuing coverage of this stock; the current analyst may or may not have covered it over the entire period.
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