Akebia (AKBA)

Rating	**OUTPERFORM* [V]**
Price (24 Oct 14, US$)	19.72
Target price (US$)	25.00[1]
52-week price range	29.17 - 16.86
Market cap. (US$ m)	399.59
Enterprise value (US$ m)	295.63

**Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.*
[1]Target price is for 12 months.
[V] = Stock considered volatile (see Disclosure Appendix).

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COMMENT

Investors Focused On The SAE Imbalances

- **Summary:** This morning AKBA released top-line results of AKB-6548 Phase IIb, CI-0007, placebo-controlled trial in non-dialysis patients with anemia related to CKD. The trial hit the co-primary endpoint defined as (1) achievement or maintenance of a mean HGB ≥11.0 g/dL, **or** (2) increase in HGB by ≥1.2 g/dL above the pre-treatment value as measured by the mean HGB value at W19 and W20, with high statistical significance. While overall safety was balanced across the arms, there were imbalances in SAEs with a higher incidence in AKB-6548 relative to placebo (23.9% vs. 15.3%). AKBA to end PII discussions with regulatory authorities in Q4:14/Q1:15 and the start of the PIII trials in mid/H2:15 (we previously assumed H1:15).
- **Efficacy data ticked the box: PIIb data shows the potential of HIFα stabilization and dosing regimen in modulating/controlling Hb levels.** The results demonstrate that 54.9% of patients who received ABK-6548 met the primary endpoint vs. 10.3% in the placebo group (p<0.0001). Only six patients (4.4%) experienced HGB excursions greater than 13.0 g/dL (with 5 having a single reading >13g/dL).
- **Imbalances in SAEs will be the focus until full granularity of the data is released in 2015.** The incidences of treatment-emergent adverse events were generally balanced between AKB-6548 (74.5%) and the placebo (73.6%) cohorts. In terms of SAEs, the most common were renal-related, with a higher incidence in the active treatment group (23.9%) vs. the placebo group (15.3%). Of the three of the 49 reported SAEs, one was classed as "probably" related to the AKB-6548 (swelling of lip/angioedema), and two "possibly" (1 LFT, 1 sudden cardiac death).

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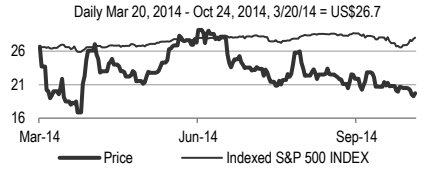
Share price performance



On 10/24/14 the S&P 500 INDEX closed at 1964.58

Quarterly EPS	Q1	Q2	Q3	Q4
2013A	—	—	—	—
2014E	-43.37	-0.39	-0.41	-0.58
2015E	—	—	—	—

Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US$)	-4.41	-7.94	-0.33	0.17
Prev. EPS (US$)	—	—	—	—
P/E (x)	-4.5	-2.5	-60.4	116.0
P/E rel. (%)	-26.0	-15.6	-421.5	904.0
Revenue (US$ m)	—	—	40.0	80.0
EBITDA (US$ m)	-15.2	-38.3	-7.7	4.0
OCFPS (US$)	-0.72	-7.29	0.26	0.83
P/OCF (x)	—	-2.7	74.5	23.6
EV/EBITDA (current)	-24.9	-7.7	-24.2	39.9
Net debt (US$ m)	-21	-104	-214	-239
ROIC (%)	-167.02	-603.03	-515.62	-72.30

Number of shares (m)	20.26	IC (current, US$ m)	9.54
BV/share (Next Qtr., US$)	—	EV/IC (x)	—
Net debt (Next Qtr., US$ m)	—	Dividend (current, US$)	—
Net debt/tot eq (Next Qtr., %)	—	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates.

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- An additional two deaths were reported in the active treatment group but not attributable to AKB-6548. Whilst management provided notable granularity on these SAE's in the call (and some assurances that they were not fundamental red flags) – there is some understandable investor focus on these and read through to the likely PIII requirements. Given that (a) we are unlikely to see further granularity on the dataset until Q1:15 at the earliest, (b) PIII set up is not likely to be disclosed until late H1:15, (c) the ongoing debate over the potentially competitive AZN/FibroGen's Roxadustat PIII requirements (LINK to 20th Aug note), and (d) concomitant likely increased financing requirements for AKBA, we can understand (if not "agree" with) today's stock price movement and concede a near/medium term stock overhang may persist. We nevertheless note the (now) *ca*$250m market cap may appeal to longer term fundamental investors and that a potential strategic partnership (for at least some geographical territories) may provide an unappreciated catalyst.

Exhibit 1: **CI-0007 PIIb Trial Design (Anemia in CKD-ND)**

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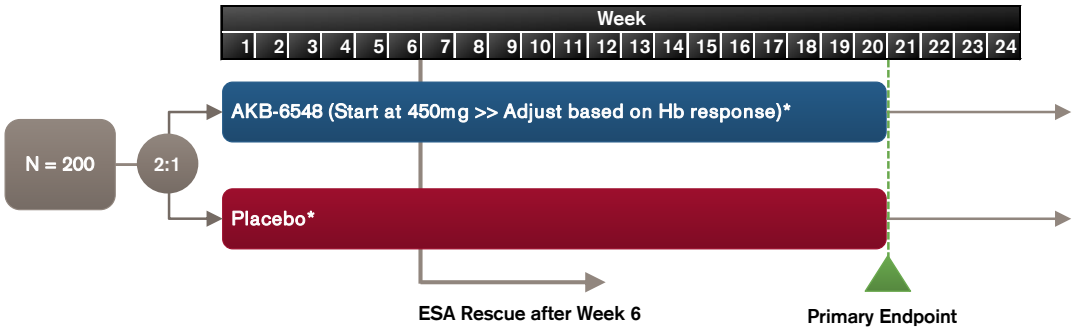
CI-0007 PIIb Trial Design (Anemia in CKD-ND)



* With Oral Iron Therapy

Locations	▪ 62 US sites
Patient Population	▪ Anemia (Hb ≤ 10.5g/dL) in CKD-ND Stages 3/4/5 ▪ Stratified into 3 patient groups – naïve to ESAs (Hb ≤ 10.5g/dL), previously treated with ESAs (Hb ≤ 10.5g/dL), or actively treated with ESAs (9.5g/dL ≤ Hb ≤ 10.5g/dL)
Primary Endpoint(s)	▪ Percentage of patients who : (1) achieve or maintain a mean Hb ≥ 11.0g/dL, or (2) increase Hb ≥ 1.2g/dL over pre-dose average Hb between screening and baseline
Key Secondary Endpoint(s)	▪ Analysis of primary endpoint by Hb control, need for rescue, baseline Hb, and pre-defined groups (20 weeks) ▪ Hematologic response (20 weeks) ▪ Need for transfusion and/or ESA rescue (20 weeks) ▪ Safety (20 weeks) ▪ Iron metabolism and utilization (20 weeks) ▪ Neurocognitive and patient-reported outcomes (20 weeks) ▪ Changes in reticulocyte Hb content, HbA1c, lipids, and functional markers ▪ Concentration measurements of AKB-6548 and glucuronide metabolites (Weeks 12 and 20)
Readout	▪ Topline PII data expected in Q4'14 (Enrollment anticipated to be complete by Q2'14)
Other	▪ Counts rescues as failures. Remove non-rescues from primary analysis.

Sources: www.clinicaltrials.gov, Akebia, Credit Suisse research

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Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 24-Oct-2014)*

Akebia (AKBA.OQ, $19.72, OUTPERFORM[V], TP $25.0)

Disclosure Appendix

Important Global Disclosures

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3-Year Price and Rating History for Akebia (AKBA.OQ)

AKBA.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
14-Apr-14	21.14	25.00	O *

** Asterisk signifies initiation or assumption of coverage.*

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Underperform/Sell*	13%	(44% banking clients)
Restricted	2%	

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Price Target: (12 months) for Akebia (AKBA.OQ)

Method: Our DCF-derived TP of $25 is based on annual cash flows through 2027, a 10% discount rate, 50% probability of success, and no terminal value. The cash flows are based solely on revenues (direct sales in the US as well as royalties in the EU and Japan) form AKB-6548 as a treatment for anemia in chronic kidney disease on dialysis (CKD-D) and not on dialysis (CKD-ND) and add-back of all R&D expenses not associated with AKB-6548.

Risk: The risks to our TP of $25 are: (1) AKB-6548 is not approved or significantly delayed. (2) AKB-6548 does not demonstrate efficacy and/or safety expected from data on studies to date. (3) AKB-6548 could underperform our expectations for the product launch ramp and/or peak sales. (4) Anemia in CKD market may not become as large as expected.

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