YM BioSciences Inc. FAQ – Calendar Q2 2009

General Corporate

Question: **What does YM expect will be some of its key developments in 2009?**

Answer: We expect that key developments for YM BioSciences in 2009 will include an extensive roll-out of important data concerning nimotuzumab's differentiation from the other marketed drugs in its class. These data are expected to lead to broad recognition and acceptance of the efficacy and safety of nimotuzumab. Important clinical data points will also be released over the next 12-18 months. Various prospective corporate events could also have material impact on the Company in 2009.

Upcoming developments are expected to include:

Publications

- AACR poster (Biocon) response data from BEST trial in head & neck cancer (April 2009)
- AACR poster (YM) confirming similarity of method of activity of nimotuzumab and Herceptin (April 2009)
- ASCO poster (Biocon) 30-month survival data in head & neck BEST trial (June 2009)

Prospective Publications

- *Journal of Cancer Research* - mechanistic differentiation of nimotuzumab and cetuximab (Q3)
- *Expert Opinion on Biological Therapy* - clinical study report on nimotuzumab-treated palliative NSCLC (Q3)
- *Journal of Thoracic Surgery* - clinical study report on nimotuzumab-treated palliative NSCLC (Q3)
- ASTRO - oral presentation BEST trial (November 2009)

Clinical Data

- Nimotuzumab European final Phase III pediatric glioma data in 2010
- Nimotuzumab European Phase III adult glioma data in 2010
- Nimotuzumab North American Phase II pediatric glioma data in 2010
- Esophageal Phase II data (Brazil) in 2010
- Nimotuzumab Phase II (Japan) gastric cancer data in 2010?

Corporate Events

- Response from the US government to commercializing nimotuzumab in the US

Question: **How does YM plan to spend its cash on hand? Do you plan to in-license any new products or dedicate your resources to nimotuzumab?**

Answer: As at March 31, 2009 the Company had cash and cash equivalents and short-term deposits approximating $45.0 million. Management believes that these resources are adequate to achieve several key clinical milestones with nimotuzumab. YM's business model is to license, develop and partner - the Company will always consider new licensing opportunities.

Organizational Structure

Question: **What is the strategic role your subsidiaries play and are there any real or perceived advantages for licensing terms, managing the trials, personnel, etc.?**

Answer: Together with its four licensees YM is, through its 80%-owned subsidiary, CIMYM BioSciences Inc., conducting (as at calendar Q1, 2009) eleven Phase II and Phase III clinical trials worldwide (Table 1). As a result of the subsidiary structure and its leadership of a consortium of nimotuzumab licensees, a number of the trials are being conducted under common protocols sharing the costs and improving the speed of recruitment. This volume of clinical activity is believed to be unique for any sub-$500 million North American development company

CIMYM is an 80%-owned Canadian subsidiary of YM; 20% is owned by the licensor of nimotuzumab and that proportion was received in exchange for a royalty-free license for most major world markets. YM recoups its investment in CIMYM from 90% of income achieved through the license (licensee fees, royalties, etc.). CIMYM has retained the rights for nimotuzumab in the US & Canada, Australia, New Zealand and Israel and has economic interests in marketing of licensees in the remainder of its territories which include all of Western and Eastern Europe, Japan, South Korea and a territory that is comprised of Indonesia, Singapore, Malaysia and the Philippines plus certain African countries.

This out-licensing strategy results in clinical data as well as important translational and pre-clinical data being shared with the consortium and a substantial volume of clinical activity being undertaken at the expense of the sub-licensees while YM retains rights to the data for its own territories.

Specifically, as at June 1, 2009:

- Daiichi Sankyo (#4568, Tokyo SE, ~US$13bn market cap) is conducting, a randomized Phase II trial in 2nd line gastric cancer, a Phase II trial in first-line NSCLC, and anticipates launching trials in additional indications.
- Innogene Kalbiotech, a wholly-owned subsidiary of Kalbe Farma (KLBF.JK, Jakarta Indonesia, US$850mm market cap - largest publicly-listed pharmaceutical company in SE Asia) has enlisted the highly regarded National Cancer Center of Singapore to conduct, at its expense, both a Phase III trial in adjuvant SCCHN and continues with a Phase II trial in locally-advanced SCCHN.
- Innogene Kalbiotech has also received marketing authorization for nimotuzumab in Indonesia, Cambodia and the Philippines.
- Kuhnil Pharma (Korea - private) is participating in the gastric trial, has participated with YM in the NSCLC trial published at ASCO 2008 and is expected to participate in YM's two randomized, double-blinded NSCLC-related trials that are currently being initiated.
- Oncoscience AG (Germany - private) is conducting a Phase III trial in adult glioma, a Phase III in 1st line pediatric DIPG, and a Phase II/III trial in pancreatic cancer.

Table 1 - Nimotuzumab studies by YM and direct licensees

Phase	Indication	Sponsor	Treatment	Status (@ doc. date)
Phase III	First-line head and neck cancer (adjuvant setting); R DB	National Cancer Centre Singapore (supported by Innogene Kalbiotech)	CT + RT ± N	710 patient - ongoing
Phase III	First-line pediatric diffuse intrinsic pontine glioma; SA OL	Oncoscience	RT + N	42 patients – recruitment completed
Phase III	First-line adult glioma; R OL	Oncoscience	RT + TZ ± N	148 patients - ongoing
Phase II/III	First-line pancreatic cancer; R DB	Oncoscience	G ± N	188 patients - ongoing
Phase II	First-line head and neck cancer; SA OL	YM BioSciences	RT + N	Completed
Phase II	Recurrent high-grade pediatric glioma; SA OL	Oncoscience	N	Completed
Phase II	Advanced refractory pancreatic cancer; SA OL	Oncoscience	N	Completed
Phase II	Irinotecan-refractory colorectal cancer; SA OL	YM BioSciences	CT + N	61 patients - completed
Phase II	First-line or later NSCLC (palliative setting);R DB	YM BioSciences	RT ± N/P	128 patients - ongoing
Phase II	First-line or later metastasis from NSCLC; R DB	YM BioSciences	WBRT ± N/P	88 patients - ongoing
Phase II	Advanced 5FU-refractory gastric cancer; R OL	Daiichi Sankyo/Kuhnil	CT ± N	80 patients - ongoing
Phase II	Recurrent pediatric diffuse intrinsic pontine glioma; SA OL	YM BioSciences	N	44 patients - ongoing
Phase II	Squamous cell carcinoma of head and neck; SA OL	National Cancer Centre Singapore (supported by Innogene Kalbiotech)	CT + RT + N	37 patients - ongoing
Phase II	Cervical cancer Stage III; SA OL	Innogene Kalbiotech	RT ± N	71 patients - ongoing
Phase II	First-line NSCLC Stage III (curative intent); SA OL	Daiichi Sankyo/Kuhnil	CRT + N	39 patients - ongoing
Phase I	First-line NSCLC (palliative setting); SA OL	YM BioSciences/Kuhnil	RT ± N	34 - patients completed
Phase I	Safety study; SA OL	Daiichi Sankyo	N	13 patients - completed
Phase I	Pharmacodynamic study; SA OL	YM BioSciences	N	16 patients - completed

Indication: DB - Double-blinded; OL - open-label; R - Randomized; SA - single-arm
Treatment: CT - chemotherapy; G - Gemcitabine; N - nimotuzumab; P - placebo; RT - radiation therapy; TZ - temozolomide; WB - whole brain

The objective of CIMYM and the licensees is to achieve the goal of a number of licensees participating in a number of different trials, thereby reducing the costs of each of the participants for each trial, increasing the number of oncologists administering nimotuzumab in each licensee's local geography and, of greatest importance, significantly reducing the time to completion of recruitment so that each indication can be rapidly cleared for marketing by each participant.

YM's personnel manage the flow of scientific, regulatory, and clinical information between the various licensees and provide critical assistance for all the material required by those licensees in their regulatory submissions. The "consortium of licensees" is coordinated through YM.

YM's current initiatives include the further expansion of its licensee network activities to embrace other nimotuzumab developers around the world (of which there are an additional eight - see below) to participate in multinational trials. Assuring standardized

GCP across a number of participants to a single, common protocol has been the rate-limiting factor which is shortly expected to be resolved. Resolution will expand the number of participating companies further speeding recruitment and reducing cost.

Table 2 - Summary of companies involved in developing nimotuzumab

Company	Rights licensed from	Territories covered	Nimotuzumab approved?
CIMAB	N/A	Cuba	Yes
YM BioSciences	CIMAB	US, Canada, Australia and New Zealand	No
Daiichi Sankyo	YM BioSciences	Japan	No
Innogene Kalbiotech	YM BioSciences	Nigeria, Congo, South Africa, Thailand, Indonesia, Malaysia, Philippines and Cambodia	Yes - Cambodia, Indonesia, and Philippines
Kuhnil	YM BioSciences	South Korea	No
Oncoscience	YM BioSciences	Europe and Russian Federation	Yes - Ukraine
Biocon	CIMAB	India	Yes
BioTech Pharmaceutical	CIMAB	China	Yes
CAIF	CIMAB	Argentina	Yes
El Kendi	CIMAB	Algeria	No
Eske Group	CIMAB	Peru	Yes
Eurofarma	CIMAB	Brazil	Yes
Laboratorias Delta	CIMAB	Columbia	Yes
Laboratorios PiSA	CIMAB	Mexico	No
Lab Genpharma*	CIMAB	Mauritania and Gabon	Yes
Libra Paraguay*	CIMAB	Paraguay	Yes
Tabuk Pharmaceutical	CIMAB	Saudi Arabia	No

Note: *Not a consortium member

Clinical Development Strategy

Question: **What is your strategy for marketing approval in the U.S. for nimotuzumab?**

Answer: YM, as the only company that has initiated a clinical trial in the US with a drug of Cuban origin and US government clearance, has applied (Q1, 2009) to the responsible US government department (U.S. Treasury's Office of Foreign Assets Control or OFAC) for a license to import nimotuzumab on an unrestricted basis in order to expand the trials that it already has initiated in Canada as well as to expand trials being conducted by other consortium members into the US. These include a pivotal international Phase III ongoing under the aegis of National Cancer Center of Singapore.

YM has a license from OFAC to import nimotuzumab into the US in order to conduct (and is currently conducting) a study of nimotuzumab in children suffering from inoperable brain cancer (DIPG - diffuse-intrinsic pontine glioma). Nimotuzumab is also available on a compassionate use basis in the United States for children with this condition. Nimotuzumab is designated an Orphan Drug for adult and pediatric glioma by the FDA as well as the EMEA.

Marketing approval will require a further license from OFAC beyond the license already obtained. Such licenses have previously been issued by OFAC although neither of the recipients initiated any clinical trials under their licenses and consequently did not file for marketing approval, as authorized

Question: **Has there been any discussion with the US FDA on this issue?**

Answer: YM has FDA clearance for both the DIPG trial and Expanded Access Program and YM has had initial discussions regarding additional trials already cleared by the health regulator in Canada.

Question: **How do the clinical trial results with nimotuzumab compare with Erbitux® and/or Vectibix® in terms of efficacy in the colorectal cancer, SCCHN and non-small-cell lung cancer indications?**

Answer: See separate answers in FAQ CRC and FAQ NSCLC

Question: **What are your plans for continuing the colorectal trial?**

Answer: YM considers the rectal indication as appropriate for treatment with nimotuzumab as the treatment regimen for rectal cancer includes radiation, which has been established as producing the elevated density of EGFR in tumors to which nimotuzumab would bind equally as the marketed antibodies. This indication represents approximately one-third of colorectal patients, but YM has no intention of continuing the original refractory colorectal indication. The evidence indicates that there is good opportunity for nimotuzumab in the large indication of rectal cancer.

Question: **What is the market size for the rectal indication?**

Answer: The market size for rectal patients treated with radiation is approximately 23,000 in North America, 20,000 in Japan, and 10,000 in Europe.

Question: **What is the market size for the glioma indication?**

Answer: The market size for glioma patients is approximately 4,800 in North America, 1,000 in Japan, and 12,600 in Europe.

Question: **What is the market size for NSCLC indication?**

Answer: The market size for NSCLC patients is approximately 166,000 in North America, 52,000 in Japan, and 229,000 in Europe.

Question: **What is the market size for the brain mets indication?**

Answer: The market size for patients with brain mets from the lung is approximately 52,000 in North America, 16,500 in Japan, and 71,000 in Europe.

Question: **What is the market size for the gastric indication?**

Answer: The market size for gastric cancer patients is approximately 29,000 in North America, 114,000 in Japan, and 171,000 in Europe.

Question: **Have the results of the BEST trial (randomized head & neck cancer trial) been published?**

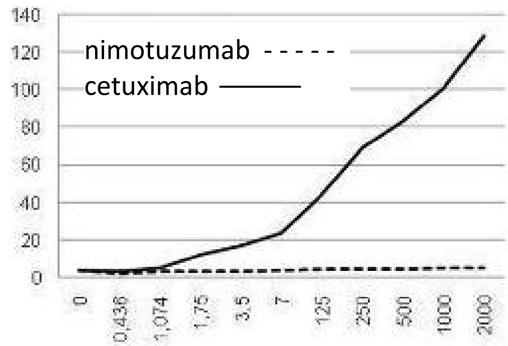
Answer: Thirty-month survival as well as response rates and other relevant measures of the BEST trial have been reported in a poster presented at ASCO 2009 showing activity in head & neck cancer competitive with Erbitux®'s data in separate trials (see *FAQ - BEST Trial*).

Question: **Several reports indicate a correlation between anti-EGFR antibody-related skin toxicities and anti-cancer responses. Does this fit with your model of nimotuzumab providing comparable efficacy in the presence of significantly reduced toxicity?**

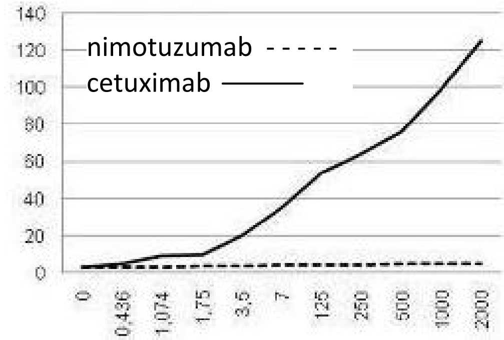
Answer: YM has presented findings that demonstrate that the efficacy of nimotuzumab and Erbitux® should be similar in tumour types with medium-to-high density of EGFR and (for the same reasons) has presented data that show that the severe toxicities of Erbitux® are not toxicities of the class - and particularly not of nimotuzumab. The bivalent binding requirement required to show the efficacy of nimotuzumab (as with Herceptin®) explains much of the improved therapeutic window for nimotuzumab compared to the other marketed therapies. The findings were described in posters presented at AACR 2008 and, together with enhanced supporting data, at AACR 2009.

In terms of the observed toxicities, it has been established that both magnesium (Mg) transport and skin inflammation are EGFR-driven. EGFR is a major housekeeping/prosurvival gene and <u>YM's findings reveal that blocking the receptor in non-tumoral tissues is detrimental</u>. YM proposes that the data supporting the AACR presentations has established that the toxicities of Erbitux® are not markers for clinical benefit at all but are principally markers of indiscriminate targeting resulting from Erbitux®'s monovalent binding. In management's view, this discovery is supported by YM's data (below) in which Erbitux® binds to normal skin and kidney cells.

HEC
Human Epidermal Cells

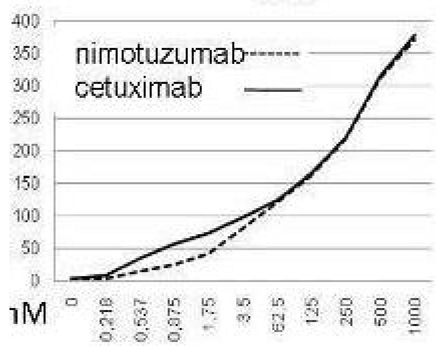


HREC
Human Renal Cortical Epithelial Cells



The affinity of nimotuzumab is lower than that of cetuximab and panitumumab, which means that binding to the target is driven by avidity, not affinity. Affinity represents the strength of a monovalent bond (one arm of the antibody binding), while avidity represents the strength of binding with two arms of the antibody, and is the product of affinity squared. Avidity of nimotuzumab is less than that of the other antibodies (10^{-16} M vs 10^{-22} M), but realistically, anything with greater than pM binding (10^{-12}M) would appear equivalent on high density cells. This has been established in comparative binding experiments.

A431 Human Epithelial Carcinoma



YM concludes that the 'correlation' of skin rash with efficacy as seen with the other antibodies may be true for those antibodies, but that this correlation is not true for nimotuzumab.

Source: YM Poster Presentation at AACR 2009

Intellectual Property

Question: **Do you have a freedom to operate opinion for nimotuzumab in the EU and US? Are there any IP issues to watch?**

Answer: Patents covering nimotuzumab are already granted in the major markets. YM is aware of the competitive patent landscape, and has obtained freedom to operate opinions where prudent.

Marketing Strategy

Question: **What is your U.S. marketing strategy for nimotuzumab? Do you intend to enter into a licensing or collaboration deal with a partner? What feedback have you received from prospective partners?**

Answer: YM intends to conduct clinical trials in the US once clearance to do so has been received from OFAC and FDA. Discussions with prospective US partners will be initiated when permitted by OFAC.

To maintain perspective, OFAC has previously issued two unrestricted licenses for Cuban-origin pharmaceutical products - one to SmithKline Beecham in 1999 and one to CancerVax Corporation in 2004. These licenses permitted the unrestricted commercialization of the drugs. However, neither SKB nor CancerVax advanced the products through the FDA. The petition by YM for an unrestricted license is, thus, not a novel request.

Question: **What is the response from ImClone/Lilly to your positioning of nimotuzumab vs. their products?**

Answer: There has not been any communication between the companies. The previous CSO (and interim CEO) of ImClone is a YM board member.

Question: **What is your marketing strategy for AeroLEF® and expected timing?**

Answer: AeroLEF is a Phase III-ready product for which YM is seeking marketing partners for the pivotal trial. It is not YM's intention to initiate the pivotal trial in the absence of a partner. Once the phase III program commences, filing the NDA/MAA would follow in approximately two years.

Question: **Are Daiichi, Kalbe, Kuhnil and Oncoscience capable of commercializing the product if it is approved?**

Answer: Daiichi Sankyo is a highly regarded international pharmaceutical company with 15,500 employees globally. Pharmaceutical revenues (2008) approximated US$8.8BN.

Kalbe Farma is the largest publicly-traded pharmaceutical company in SouthEast Asia. Headquartered in Indonesia, the territories it has for nimotuzumab also include Malaysia, the Philippines, Singapore and three African countries including South Africa. Kalbe's revenues (2008) approximated US$700MN.

Kuhnil is the sixth largest national pharmaceutical firm in Korea and it has the ability to market in that important territory.

Oncoscience AG, or OSAG, was founded by the Managing Director of MEDAC GmbH, following an extensive career in cancer product marketing. MEDAC is a specialty pharmaceutical company focused on oncology and auto-immune product marketing, which was 25% owned by Schering AG.

The sublicense to OSAG by CIMYM permits OSAG to sublicense the further marketing of nimotuzumab in that very extensive territory.

Manufacturing

Question: **Are there any CMC issues currently outstanding with the FDA?**

Answer: Nimotuzumab is manufactured at CIM in Havana and is supplied from there to YM's majority-owned subsidiary CIMYM for its trials in the US, Canada and elsewhere and for the trials of its licensees in Japan, Europe, Korea, and Southeast Asia/Africa. The facility has been shown to be GMP-compliant and the first marketing application which will result in a health-regulatory audit from a major market country is likely to occur from Europe or Canada possibly during 2011.

CIM has two other joint-ventures - one with the highly regarded public company in India, Biocon Ltd. (BSE #532523 - market cap US$500mm) which is manufacturing the product in its facility in Bangalore, India's newest and largest biomanufacturing plant. We anticipate that Biocon could submit to an FDA audit for marketing-readiness during 2009.

The product is also manufactured by a CIM joint-venture in Beijing but the GMP status is unknown.

Question: **Who has manufactured your current clinical material? Have you already made enough clinical material to supply the remainder of your clinical development?**

Answer: As above. The manufacturing facility at CIM is capable of supplying all of YM's and YM's licensees' clinical requirements.