Clinical Research Update

I. Roswell Park Cancer Centre Update (July 27/08)

This is an update on the status of two studies that are becoming available to mCRC patients at Roswell Park Cancer Centre in Buffalo, as provided by clinician and oncologist Dr. Marwan Fakih.

1. **Insulin Growth Factor Receptor Inhibitor (IMC-A12) + Cetuximab**: opened at Roswell Park the week of May 26. The study is open in 4 centers and accrual is competitive (20 in total – potentially increasing to low 30’s).

   Enrollment requirements are as follows:
   - Patient must have responded/stabilized (min 24 weeks) to cetuximab.
   - Eventually, the patient must have failed cetuximab therapy as evidenced on CT scans.
   - A minimum of 6 weeks needs to go by before enrolling in the IMC-A12 after having failed cetuximab therapy.
   - The patient’s tumour needs to be Kras wild type (i.e., do not have the Kras gene mutation).

   The study supplies both drugs. Testing for the tumour can be done as part of the screening of the study and Dr. Fakih is looking into the feasibility of performing labs/CT in Canada for Canadian residents. A full description of the clinical study may be obtained by clicking the following link:

   www.roswellpark.org/Patient_Care/What_Is_a_Clinical_Trial/ClinicalTrialsOnlineSearch/ClinicalTrialsOnlineSearchDisplay?trial=1301&search_for=BodyPart&search_string=Colorectal&search_for2=&Active=&program_search=false

2. **High Dose Cetuximab (double) + Irinotecan in Patients Who Previously Responded to Cetuximab Therapy**: will be opening in approximately 3 months.

   - Cetuximab will be provided by the study.
   - Tumour that is Kras wild type.
   - Patient has clinical documentation of disease progression during treatment or within 6 weeks after receiving the last dose of a therapeutic regimen for metastatic disease containing an anti-EGFR-component (cetuximab or panitumumab).
   - Toxicity or planned treatment break will not be regarded as adequate evidence of disease progression and such patients will not be eligible for this trial.

   Study description will be forthcoming.