Clinical Trial Landscape in Breast Cancer – Activities and Challenges Now and in the Near Future

**Key Conclusions**

- High proportion of survey respondents are currently participating in clinical trial research
  - Information in this report is representative of this segment of the breast cancer community
- Respondents were from a sample across all disciplines, including group practices, community hospitals and academic centers

**Additional Information**

- “Current” is defined as having participated as an investigator within the past 2 years
Disproportional Relationship between Clinical Trial Participation and Disease Prevalence

Key Conclusions
- Over 1/2 of survey respondents are involved in clinical trial research on metastatic breast cancer
- Discordance between physician involvement and patient population
  - Inflammatory breast cancer has the highest difference

Additional Information
- “Current” is defined as having participated as an investigator within the past 2 years
- Stage Prevalence determined from self-reported patient flow
Physician Interest in Clinical Trial Participation Extends Throughout Every Stage of Breast Cancer and Outpaces Current Participation

Desired Participation in Future Breast Cancer Clinical Trials by Stage

- Carcinoma in situ
- Early / Locoregional
- Locally Advanced
- Inflammatory
- Metastatic

Key Conclusions
- Increased physician interest in clinical trial involvement for all disease stages
- Metastatic breast cancer has smallest difference between current and future
  - Saturation in participation levels?
- Desired interest significantly outpaces actual participation
  - Is there sufficient availability of suitable patients to feed adequate recruitment levels

Additional Information
- “Current” is defined as having participated as an investigator within the past 2 years
- “Future” is defined as within the next 2 years
Institutional Involvement in Breast Cancer Clinical Trials

Key Conclusions

- Most institutions are participating in a select few clinical trials
- Only a small number of clinicians at these institutions are involved in the clinical trials
- About 20% of institutions are involved in a large number of clinical trials for breast cancer
  - Even at these “high-participation” institutions, only a limited number of physicians are involved in these clinical trials
- Is patient volume significantly large to ‘feed’ these trials?
Wide Variety of Laboratory Capabilities in Support of Clinical Trials

**Key Conclusions**

- No “universal” laboratory function available in-house
  - Diagnosis / staging was most prevalent at ~ 70%
- A central laboratory may be needed for genotyping and protein analysis within a clinical trial
- Every survey respondent’s institution was performing some type of laboratory function for a clinical trial

**Additional Information**

- Data shown as a percentage of all survey respondents
- Respondents could select as many choices as applicable
Having the “Correct” Patients is the Biggest Challenge for Physicians to Participate in Clinical Trials

Key Conclusions

- The main factor preventing additional participation in clinical trials is having the patients available that fit the study’s inclusion criteria
- Physician compensation is an important factor
- Institutional factors (equipment, capacity, laboratory, etc.) are NOT major detriments

Additional Information

- Each factor was ranked on importance by respondents
- Relative ranking calculated as the percentage of maximum score possible
Conclusions about Physician Involvement in Clinical Trials for Breast Cancer

• Nearly 3/4 of survey respondents are currently involved in clinical trial research for breast cancer

• For most stages of breast cancer, physician involvement in clinical trials is greater than what would be predicted from stage prevalence
  – Greatest physician involvement in studies for metastatic disease
  – Patient volume appears inadequate to feed current trial activity, especially in metastatic and inflammatory disease

• Significant interest in additional clinical trial participation across all stages of breast cancer
  – Metastatic disease may be nearing saturation
  – Is patient volume sufficient and adequate to feed future trial recruitment requirements?

• Most institutions run limited number of different clinical trials involving select faculty

• While ALL institutions have some capacity to provide laboratory support to clinical trials, no methodology in “universally” available
  – Use of central laboratories should be considered for genotyping and protein analysis within a clinical trial due to their limited availability

• Biggest challenge for physicians to participate in a breast cancer clinical trial is having the patient population that fits the study design
  – Physician compensation is an important driver to physician participation