A Canadian Registry of FOLFIRINOX in Advanced/Metastatic Pancreatic Cancer

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Background: Clinical trial results are usually not validated once a regimen is introduced in clinical practice. The efficacy, tolerability, and quality of life of FOLFIRINOX (5-fluorouracil, leucovorin, irinotecan, and oxaliplatin) were demonstrated in the ACCORD clinical trial (Conroy et al, NEJM 2011). Concerns were related to safety, particularly neutropenic sepsis. Knowledge about oncologists’ implementation approach of this regimen, and clinical management and outcomes of patients receiving FOLFIRINOX combination in clinical practice could help improve on treatment delivery options.

Methods: Members of the Canadian Association of Medical Oncologists were invited to participate in a registry to collect information on the treatment and clinical course of patients with advanced/metastatic pancreatic cancer treated with FOLFIRINOX in a regular clinical setting. Data for the planned 200 registry patients is collected via a commissioned web-based collection system. The registry covers all consecutive consenting patients with pancreatic cancer who have completed at least one cycle of FOLFIRINOX. Demographic information, treatment exposure, dose adjustment, adverse events, and efficacy data are collected. The data management team at The Ottawa Hospital Cancer Centre (TOHCC) reviews all data entries to ensure proper quality control.

Results: Thirty oncologists with expertise in the treatment of pancreatic cancer, representing 17 academic/university centers from 6 Canadian provinces confirmed participation. As of March 2013, the pilot site (TOHCC) has identified 41 patients treated with FOLFIRINOX; 5 sites representing 4 Canadian provinces are close to obtaining ethical approval. Of 31 (75%) patients eligible for the registry (median age: 31 years, range 19-68) 30% were female. 40% of patients are alive with a quarter of them still on FOLFIRINOX.

Conclusion: A well represented pan Canadian registry was developed to collect information on patients with pancreatic cancer who are receiving treatment with FOLFIRINOX in regular clinical setting. The experience demonstrates that the creation of a comprehensive, collaborative clinical setting confirmatory registry is feasible and needed to assess new therapeutic interventions constituting a potentially powerful clinical and research tool. These initial registry data are valuable to provide information on treatment trends. Additional data will further describe how FOLFIRINOX is managed in routine standard practice across different centers and will identify differences between treating physicians and institutions, as newer therapeutic options become available. As the sample size grows, the registry will be increasingly suited to look at factors affecting treatment with FOLFIRINOX. A national clinical practice evaluation will provide additional data to support the use of FOLFIRINOX in locally advanced pancreatic cancer. Supported by sanofi-aventis Canada.