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ScienceDirect
Cancer Letters 249 (2007) 1–2
CANCER Letters
www.elsevier.com/locate/canlet

Foreword

Cancer biomarkers

Over the last 10 years, there has been widespread interest in the discovery and implementation of cancer biomarkers in clinical practice. Much of this interest has been fueled by the emergence of modern and powerful analytical techniques – such as mass spectrometry and microarrays – and by the completion of the sequencing of the human genome. Diverse teams of researchers from the diagnostic and pharmaceutical industries as well as academic and hospital settings have invested enormous effort and resources in attempts to develop novel cancer biomarkers. Funding agencies have responded with the launch of numerous special programs related to cancer biomarkers in the hope that new advances in this field will lead to earlier diagnosis, individualized therapy and better indicators of prognosis. All this, it is hoped, will lead to better patient management and improved clinical outcomes.

Unfortunately the promise has yet to be fully realized. Despite the magnitude of the effort and the invested funds, no new diagnostic biomarkers have made it into the clinic for at least 10 years, though a number are currently in development. Many experts now believe that the challenges associated with discovery and validation of new tumor markers may have been underestimated. For example, it is now clear that the discovery phase for cancer biomarkers typically takes 3–5 years, with the validation of candidates and their introduction into the clinic requiring an additional 5–10 years. Most candidate cancer biomarkers fail validation and the rigorous regulatory criteria governing introduction into the clinic. The final yield is very low.

Nevertheless, cancer biomarkers have facilitated the development of a number of successful treatments now available in common practice or undergoing late phase III clinical trials involving disease specific subpopulations selected on the basis of distinctive biomarker profiles (e.g. trastuzumab and imatinimab mesylate). Another promising advance is the recent FDA approval of biomarkers for the purpose of predicting medication toxicity, as in the case of the UGT1A1*28 allele whereby homozygosity increases risk of neutropenia in the setting of irinotecan treatment. Thus, the application of cancer biomarkers to clinical care is progressing, albeit more slowly than originally anticipated, and there are some grounds for cautious optimism of further advances in this challenging field.

We and others have previously published 'special issues' on cancer biomarkers [1–4] and drafted guidelines for their use in the clinic [5]. In the present undertaking, we have assembled papers that provide novel insights into established and investigational biomarkers with emphasis on the discovery process, validation and application to clinical practice. Included are reviews of the tissue kallikreins (Paliouras et al.) and survivin (Duffy et al.), promising new markers with relevance across numerous different cancers. Three reviews deal with prostate cancer diagnostics (Reynolds et al.; Stephan et al.; Loeb and Catalona), including issues related to the optimization of PSA testing methods. Other reviews address biomarkers for colon cancer (Booth) and ovarian cancer (Robertson et al.). The remaining papers review various methodological strategies for discovering and validating biomarkers. Hanash's group and Gunawardana and Diamandis outline how autoantibodies can be used for cancer diagnosis. Bayani and Squire describe the use of FISH in biomarker research. Tammen et al. examine the use of oncopeptidomics techniques in biomarker discovery.

We hope that the papers selected for this special issue of Cancer Letters individually address impor-

0304-3835/$ - see front matter
doi:10.1016/j.canlet.2006.12.033

tant developments across the field of cancer biomarker diagnostics, discovery and validation, and collectively provide a realistic overview of the sort of practical advances that can be anticipated in the recent future.

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K.R. Evans[1]
Ontario Cancer Biomarker Network, MaRS Centre, South Tower, 101 College Street, Suite 200, Toronto, ON, Canada M5G 1L7
E-mail address: kevans@ocbn.ca

B.R. Hoffman[2]
Department of Pathology and Laboratory Medicine, Mount Sinai Hospital, 600 University Avenue, Toronto, ON, Canada M5G 1X5
E-mail address: bhoffman@mtsinai.on.ca

E.P. Diamandis[*]
Department of Pathology and Laboratory Medicine, Mount Sinai Hospital, 60 Murray St., Box 32 [RM L6-201], Toronto, ON, Canada M5T 3L9
E-mail address: ediamandis@mtsinai.on.ca

[*] Corresponding author. Tel.: +1 416 586 8443; fax: +1 416 361 2655.
[1] Tel.: +1 416 673 6693.
[2] Tel.: +1 416 586 4463; fax: +1 416 586 8628.