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Subsequent entry biologic (biosimilar) monoclonal antibodies in Canada: A review of key regulatory issues and lessons learned

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Subsequent Entry Biologics (SEBs) or biosimilars are more commonly known as biotherapeutic products that enter the market subsequent to a previously authorized biotherapeutic to which they have been proven to be highly similar. Monoclonal antibodies represent the most complex of these molecules manufactured to date. For these products, similarity should be rigorously proven from physicochemical and biological perspectives and should be supported by similarity in clinical pharmacology, clinical efficacy, safety and immunogenicity. Health Canada authorized its first monoclonal antibody biosimilars in 2014 and has since begun reviewing other proposed biosimilars mAbs for market authorization. This increased activity coincides with the recent expiration of patents and exclusivities for many of the first innovative monoclonal antibody products. The speaker will discuss the approach that Health Canada takes to the review and authorization of monoclonal antibody biosimilars, lessons learned since the publication of the guidance document Guidance for sponsors: Information and submission requirements for subsequent entry biologics (SEBs) in 2010 and recent efforts to update the guidance based on our experiences with biosimilar submissions. Key issues such as the use of a non-national reference product, immunogenicity and extrapolation will be highlighted.

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Expression of CD31 and CD34 in oral squamous cell carcinoma development and metastasis

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Aim: The aim of this study was to compare two endothelial markers (CD31 and CD34) and to clarify the role of angiogenesis in Oral Squamous Cell Carcinoma development and metastasis.

Material & Methods: We have performed a retrospective analysis on 50 human OSCC bioptic specimens, using immunohistochemical analysis with anti CD31 and anti CD34. Mean values of these two antibodies were compared as well as possible correlations between peritumoral microvessel density and clinico-pathological parameters were evaluated, such as age, sex, tumor localization and size, lymph node status and histological grading.

Results: The peritumoral MVD count per high power field (1 mm2) in all 50 tumors detected by antibodies CD31 and CD34 ranged 4 to 27 and 13 to 58, respectively, with means of 13.74 and 22.75, respectively. The peritumoral MVD determined using CD34 were significantly associated with age (P=0.027), the peritumoral MVD using CD34 and CD31 immunostaining of OSCC with a lymph node metastasis was higher than with a negative node status with means of 15.04 and 12.55 respectively for the CD31, 24.61 and 21.44 respectively for the CD34. However, no statistical correlation was observed between peritumoral microvessel density and other clinical parameters such as sex, tumor site, size, lymph node status and histological differentiation.

Conclusion: According to our study, tumor angiogenesis and the density of newly formed vessels are of potential prognostic relevance in the assessment of OSCC and we showed that the endothelial marker CD34 was better in the assessment of tumor vascularization of OSCCs than CD31.

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