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It is our great pleasure to present this Supplement Issue on "*Macedonian Pharmaceutical Bulletin*" to the scientific and professional community. This supplement includes the short communications from the *Sixth Congress of Pharmacy in Macedonia with International participation*, as the largest gathering for the pharmacy profession held in the Republic of Macedonia. The main theme of the Congress was "Modern pharmacist - bridging science with practice".

A broad spectrum of topics within the pharmaceutical sciences and practice carefully selected for this special occasion in order to build up a highly interesting and comprehensive program were covered. The contributions submitted to the Congress included 6 plenary lectures, 84 section lectures, and more that 240 posters. This Congress, followed the excellent international tradition, was attended by close to 1000 domestic and foreign participants. We received 326 short paper submissions from more than 25 countries. These numbers show that our Congress is aiming for the highest scientific standards, and that it can be considered a well-established venue for researchers in the broad fields of Pharmaceutical sciences and practice.

We would like to thank all internationally prominent researchers for their contribution to reinforcing the overall quality of the Congress. They give the state of the art of the recent advances in the field of pharmacy research.

Sincere thanks to the hosts of the Sixth Congress of Pharmacy in Macedonia with International participation, Macedonian Pharmaceutical Association and Faculty of Pharmacy, Ss Cyril and Methodius University in Skopje for their vision and commitments.

We acknowledge the sponsoring companies: the platinium sponsor AD ALKALOID, Skopje, the golden sponsor PLIVA, the silver sponsor EUROFARM and the bronze sponsor SEPTIMA, for the permanent support to our efforts during the organization.

We would also like to thank our members of the Scientific Committee for their volunteer time and dedication to the critical peer review process and in the organization of the program. We also wish to thank all the members of the Organizing Committee, whose work and commitment was invaluable.

On behalf of the Advisory and Scientific Committees, we would like to especially thank the authors, whose work was the essential part of the congress and contributed to a very successful event. Besides the many academic staff and professionals who contributed to the success of the Congress, we are grateful to the students who participated with oral presentations and posters.

The pharmaceutical sciences continue to grow as dynamic scientific interdisciplinary fields. We believe that published short communications will be an excellent source of scientific material in the fast evolving fields in Pharmaceutical sciences and practice.

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The present issue *of Macedonian Pharmaceutical Bulletin* is a special issue of the 6th Congress of Pharmacy in Macedonia with international participation.

This issue of *Macedonian Pharmaceutical Bulletin* contains short papers accepted by the scientific committee for the presentation at the Congress.

The authors are fully responsible for the contents of their short papers.

All reviewers that were involved in the short papers revision process are sincerely acknowledged.

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Short communication

Preclinical studies for evaluation of antitumor effects and normal tissue toxicity of antibody conjugates

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Introduction

Antibody conjugates are therapeutics that function through mediating alterations in antigen or receptor function, modulating the immune system (for example, changing Fc function and T cell activation) or delivering of a specific drug conjugated to antibody that targets a specific antigen (Scott et al., 2012; Weiner et al., 2010). Four main classes using antibodies are investigated to target cytotoxic agents to cancer cells: antibody-protein toxin conjugates, antibody-chelated radionuclide conjugates, antibody–small-molecule drug conjugates, and antibody-enzyme conjugates (administered together with small-molecule prodrugs) (Teicher and Chari, 2011). Only antibody-radionuclide conjugates and antibody-drug conjugates have reached the regulatory approval stage. Radio immunotherapy, exploits the specificity of an antibody to deliver a radionuclide, and affords some potential benefits over conventional radiotherapy. Antibody-radionuclide conjugates have been successfully developed for the treatment of non-Hodgkin's lymphoma (NHL), resulting in the approval of 131I-tositumomab (Bexxar) and 90Y-ibritumomab tiuxetan (Zevalin), which are CD20-targeted agents (Maloney et al., 2010). Important steps that are necessary to transform monoclonal antibodies (mAbs) in drugs for human use must be followed to achieve success in treatment of cancer patients with antibodies. Furthermore, dealing with the challenges in the process of target selection and selection of conjugate elements including the design of antibody formulation is also imperative.

Development and evaluation of antibody conjugates

The successful development of candidate antibodies involves complex evaluations, concerning cancer biology and the properties of antibodies in vivo. Essential preclinical characterization includes identification of the physical and chemical properties of the antibody; detailed analysis of antigen expression using normal and malignant tissues; study of the immune effector functions and signaling pathway effects of the antibody; toxicity assessment; analysis of in vivo antibody localization and distribution in tumor systems; and observation of the in vivo therapeutic activity of the antibody, alone or conjugated with radioactive isotopes or other drugs.

In case of NHLs, the biodistribution studies of a radioconjugate in the tumor tissue and an assessment of whole-body toxicity and dosimetry were essential in preclinical trials leading to approval of CD20 specific radioimmunoconjugates tositumomab and ibritumomab for treatment by US Food and Drug Administration (FDA) (de Bono and Ashworth, 2010). Rituximab also has considerable success in treatment of patients with CD20 positive NHL and chronic lymphocytic leukemia. Radioimmunotherapy with rituximab labeled with suitable radioisotopes, is new opportunity after promising preliminary results where preclinical data demonstrated improved tumor response (Scott et al., 2012).

Toxicity studies

One of the most essential steps in the evaluation of a potential diagnostic/therapeutic antibody is determination of the toxicity of an antibody (often radiolabelled) and the ratio of antibody uptake in the tumor versus normal tissues. This information is essential for the rational design of antibody conjugates therapy, where uptake of antibodies by normal tissues is crucial for predicting toxicity on one side, but also is crucial for defining dose regimen where optimal tumor concentration of the antibodies will be achieved on the other.

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Normal and tumor tissue distribution can be quantified and evaluated by toxicity studies in animal models, where kinetics, distribution and induced effects in mice/rats or other nonrodent species, with or without implanted tumor are followed. These studies include administration of selected doses of radiolabelled mAbs and monitoring of tumor growth or survival of animals over time (Reilly et al., 2006). A control group of animals receives only the solvent of the formulation or non-specific radiolabelled mAbs of the same class. Generalized and gastrointestinal toxicity is followed by the weight monitoring (significant weight loss > 10-20%), while bone marrow toxicity is assessed by hematology analyses including leukocyte (WBC), erythrocyte (RBC), and platelet counts as well as hematocrit (Hct) and hemoglobin (Hb) concentrations. Biochemistry analyses included serum alanine aminotransferase (ALT) for liver toxicity and creatinine (Cr) levels for renal toxicity. In addition, samples from different tissues (liver, kidneys, etc) are obtained for hystopatological examination by light or electron microscopy. Potential radiotherapeutic agent should demonstrate specific anti-tumor effects targeted only tumor tissue with only minimal to moderate toxicity to normal tissues.

Conclusions

Varied and newly designed antibody conjugates are currently directed toward various tumor targets in clinical trials, and more are nearing clinical trial. Before reaching any possibility for patient's treatment, successfully passed preclinical phase is essential. The future development of antibody conjugates as therapeutics in cancer treatment is dependent on data from laboratory studies, on applying innovative approaches to target and antibody selection and on appropriate development strategies, leading at the end, to clinical benefit in cancer patients.

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