

**Haematology and secondary hypertension:
pioneering applications of CXCR4 diagnostics and treatment
(PentixaPharm satellite symposium 9/2023)**

Würzburg/Vienna 21.09.2023 - As part of the Annual Conference of the European Association for Nuclear Medicine (EANM), international experts taking part in the PentixaPharm satellite symposium presented promising clinical study data for the first time on the use of the key substance [⁶⁸Ga]Ga-PentixaFor (international non-proprietary name Gallium (68Ga) Boclatafortide) in secondary hypertension. They also provided an overview of the highly promising results that have been achieved so far with [⁶⁸Ga]Ga-PentixaFor as a treatment-deciding imaging agent for primary staging in marginal zone lymphoma.

CXCRT diagnostics change stage classification in indolent lymphomas

Non-Hodgkin's lymphoma (NHL) is one of the most common forms of lymphoma, being diagnosed in around 20,000 people in Germany every year.¹ One sub-form of NHL is indolent marginal zone lymphoma (MZL)², which is more difficult to diagnose and characterise with established methods. Here, studies at the University of Würzburg have been using CXCR4-guided imaging diagnostics to facilitate a more precise staging classification and personalised treatment. Retrospective clinical data shows the staging classification and consequently also the treatment of patients with MZL can be made more precise through CXCR4-guided diagnostics. [⁶⁸Ga]Ga-PentixaFor in particular improves the primary staging of these highly heterogeneous lymphomas. "With our retrospective data, we are able to show that the concept works. We are now delighted to be able to also investigate this property in real time in an international prospective, multi-centre phase III study", says Prof. Andreas Buck, Director of Nuclear Medicine at the University of Würzburg. CXCR4-based diagnostics also offer the ability to identify patients who may benefit from radio ligand therapy with [⁹⁰Y]Y-PentixaTher. Prof. Buck particularly highlighted the data from five patients with refractory T-cell lymphoma who had already been treated successfully with [⁹⁰Y]Y-PentixaTher.

¹ https://www.krebsdaten.de/Krebs/DE/Content/Krebsarten/Non-Hodgkin-Lymphome/non-hodgkin-lymphome_node.html

² https://www.krebsdaten.de/Krebs/DE/Content/Krebsarten/Non-Hodgkin-Lymphome/non-hodgkin-lymphome_node.html

Prof. Buck also announced the forthcoming publication of EANM guidelines on CXCR4-based diagnostics and treatment. This gives hope that CXCR4-based theranostics will soon make their way into everyday clinical practice.

More precise and less invasive treatment methods thanks to CXCR4-based PET-CT imaging in primary hyperaldosteronism

A further area of focus at the symposium was the use of [⁶⁸Ga]Ga-PentixaFor as a non-invasive imaging technique capable of identifying patients with primary hyperaldosteronism (PA). Primary hyperaldosteronism is the most common cause of secondary hypertension and, despite a mean prevalence of 5% - 15%, often goes undetected.³

Dr Elisabeth Ng, endocrinologist at the Hudson Institute of Medical Research and Monash University, Australia, surprised the audience with epidemiological data on the prevalence of PA and confirmed the urgent need for medical action in the treatment of this condition. She set out the advantages for both doctors and patients of CXCR4-guided diagnostics with [⁶⁸Ga]Ga-PentixaFor in the sub-typing of patients with primary hyperaldosteronism. The use of [⁶⁸Ga]Ga-PentixaFor allows for more precise and less invasive lateralisation of patients, which is key for subsequent, potentially curative surgical treatment.

Prof. Martin Gotthardt, University Medical Center Radboud University Nijmegen, Netherlands, presented the first clinical data from the two-stage CASTUS study. This is a randomised, controlled diagnostic study comparing [⁶⁸Ga]Ga-PentixaFor PET/CTs with the previous method of selective adrenal vein blood sampling (AVS) for lateralisation of the adenoma. Since the part I data of the study has already been found to be so positive in favour of PentixaFor PET/CT, Prof. Gotthardt is certain: "If, in the second part of the study, the PET/CT is also even just as good as AVS at lateralising the adenoma, then AVS can be replaced as the current diagnostic standard. AVS is not only much more expensive, but it is also much more arduous for the patient (long investigation procedure, high radiation exposure, long waiting times due to limited capacities) than [⁶⁸Ga]Ga-PentixaFor PET/CTs." Preparations are already well underway for the CASTUS part II study, with potential expansion to European countries being discussed.

³ Study Heterogeneity and Estimation of Prevalence of Primary Aldosteronism: A Systematic Review and Meta-Regression Analysis | The Journal of Clinical Endocrinology & Metabolism | Oxford Academic (oup.com)

CXCR4 is the new, exciting theranostic target

The symposium highlighted the fact that CXCR4-based theranostics have the potential to significantly change the medical landscape. Dr Hakim Bouterfa, Head of Clinical Research and Director at PentixaPharm, expressed his satisfaction at the progress achieved: "The results we have obtained offer patients a potential return to a better quality of life and fewer medications. We are highly motivated and doing everything we can to push this development forward and

make it available to patients. We feel ourselves extremely fortunate to know that we have renowned institutions and leading clinicians by our side as we pursue the same goal." Despite extensive impressive retrospective data, further prospective clinical studies are needed for [⁶⁸Ga]Ga-PentixaFor to receive EU-wide market approval and be made available to a broad patient base. To achieve this goal, PentixaPharm is now, in conjunction with international universities, launching an extensive study programme that may lead to these highly promising radiopharmaceutical products being licensed sooner.

Prof. Ken Herrmann, moderator of the symposium and Clinical Director of the Department of Nuclear Medicine at the West German tumour centre in Essen, is convinced that "new theranostic concepts are boosting nuclear medicine. In the search for the next exciting target, CXCR4 is one of the front-runners since it can change the clinical standard both in diagnostic terms for benign conditions, but also in therapeutic terms for multiple malignant diseases."

About PentixaPharm

PentixaPharm AG, based in Würzburg and Berlin, was founded in 2019 as a medical start-up and, since June 2022 and with a workforce of over 25 people, has been part of Eckert und Ziegler Strahlen- und Medizintechnik AG. With around 1000 employees, Eckert & Ziegler is a world leader in the development and production of isotope technology components for medical, scientific and measuring technology applications. PentixaPharm is developing a theranostic process with the aim of improving the diagnostic imaging and treatment of oncological and inflammatory conditions. The associated radiopharmaceuticals [⁶⁸Ga]Ga-PentixaFor ([⁶⁸Ga]-Boclatixafortide) (diagnostic agent) and [⁹⁰Y]Y-PentixaTher ([⁹⁰Y]-Anditixafortide) (therapeutic agent) target the CXCR4 receptor, which is expressed on specific tumour tissue, and especially that of the haematopoietic system. [⁶⁸Ga]Ga-PentixaFor is based on a peptide that can specifically label the tumour tissue by binding to the CXCR4 receptor. Once the tumour has been localised, [⁹⁰Y]Y-PentixaTher is used. This therapeutic agent can destroy local tumour cells and therefore cause less tissue damage than conventional chemotherapy drugs.

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