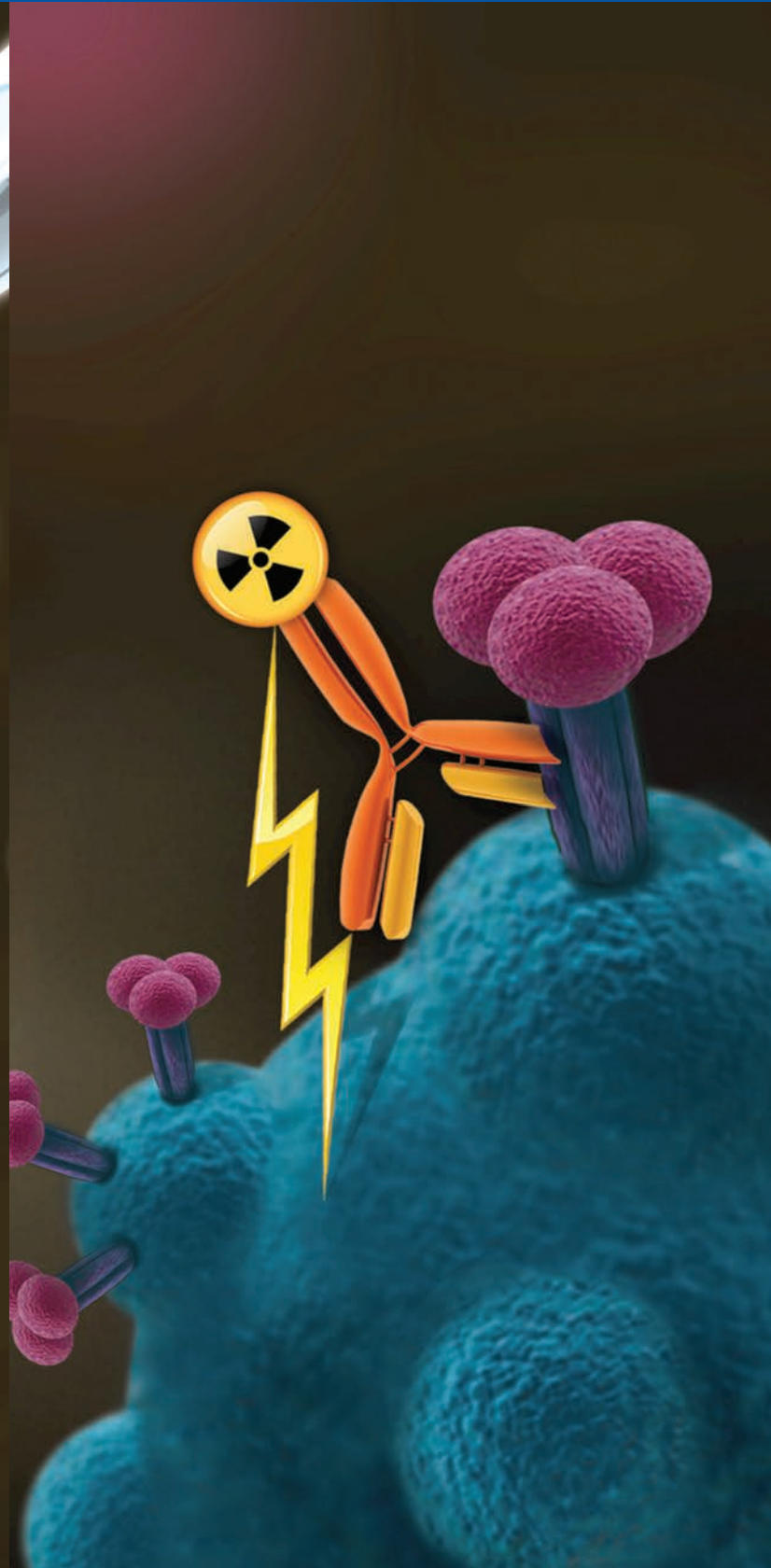


## Bioconjugation Expertise\*





## Antibody (and recombinant protein) : Drug Conjugation Capabilities

GBI has a long history of designing and manufacturing many Antibody (and recombinant proteins): Drug Conjugates.

- Proof of concept, development and GMP manufacturing of monoclonal antibodies and recombinant proteins conjugated onto small molecule cytotoxic drugs, plant toxins and other reagents
- Attach various chelators to proteins, for ultimate radiolabeling at the clients' clinical trial sites. Chelators that we have conjugated to clients' protein include CHX-A'' DTPA, DOTA, and TCMC

Clients	Clinical application / Project status	Chelator/Payload	Isotope Utilized by Client
Client 356	Immunotherapy/Proof of concept	Recombinant protein-Small molecule cytotoxic drug	N/A
Client 353 (See GBI press release.)	Radio-immuno diagnostics/ Phase I	CHX-A'	In <sup>111</sup>
Client 345	Radio-immunotherapy/Phase I	CHX-A''	In <sup>111</sup>
Client 340	Radio-immunodiagnostics and therapy/Tox (preclinical)	CHX-A''	Bi <sup>213</sup>
Client 339 (See GBI press release.)	Radio-immunotherapy/Phase I	TCMC	Pb <sup>212</sup>
Client 312 (See GBI press release.)	Radio-immunotherapy and diagnostics/Phase IA and IB	Direct conjugation onto the mAb	Re <sup>288</sup>
Client 294	Immunotherapy/ Proof of concept	Antibody-Small molecule cytotoxic drug	N/A
Client 243	Radio-immunotherapy and diagnostics/ Phase I	DOTA	Lu <sup>177</sup>
Client 237	Immunotherapy/Phase I	Antibody-plant protein toxin conjugate	N/A
Federal Gov. (several projects completed)	Radio-immuno therapy/ Phase I	CHX-A''	Bi <sup>213</sup> , In <sup>111</sup>

## GBI Selected publications on bioconjugation

E. Dadachova, E. Revskaya, M. Sesay, H. Damania, R. Boucher, et al. Pre-clinical evaluation and efficacy studies of a melanin-binding IgM antibody with <sup>188</sup>Re against experimental human metastatic melanoma in nude mice. **Cancer Biology and Therapy**. 2008; 7(7): 1116-1127

E. Dadachova, E. Revskaya, M. Sesay, R. Howell, G. Thornton, et al. Pre-clinical development of a <sup>188</sup>Re labeled melanin-binding antibody for phase I clinical trial in patients with metastatic melanoma. **J Nuclear Med**. 2008; 49 (Supplement):327P

Sesay, M.A. Monoclonal Antibody Conjugation via Chemical Modification. **BioPharm International**. 32–39, (December 2003).

Pincus S, et al. Evaluation of Antigen based Heteropolymer (AHP) for Treatment of Systemic Lupus Erythematosus in a Non-Human Primate Model. **Clinical Immunology**. 2002; 105: 141–154.

## GBI Patents pending on bioconjugation and radio isotope labeling

E. Dadachova, A Casadevall, M. Sesay, H. Damania, and P. Smariga, **Radiolabeled monoclonal antibodies using TCEP, and uses thereof**, US Patent Application number 61/000,795; 2008. (Patent Pending); Also patent pending filed with World, Canada, Australia, Japan, Europe and other countries.

E. Dadachova, A Casadevall, M. Sesay, H. Damania, and P. Smariga, **Disposable column system for purification of radiolabelled polypeptides**, World Intellectual Property Organization Patent, 2009, Publication number WO/2009/058737, Application number PCT/US2008/081337; Also patent pending filed with US, Canada, Australia, Japan, Europe and others.

## Selected publications on bioconjugation in which GBI was mentioned

Vallabhajosula S, Kuji I, Hamacher KA, Konishi S, Kostakoglu L, Kothari PA, Milowski MI, Nanus DM, Bander NH, Goldsmith SJ. Pharmacokinetics and biodistribution of <sup>111</sup>In- and <sup>177</sup>Lu-labeled J591 antibody specific for prostate-specific membrane antigen: Prediction of <sup>90</sup>Y-J591 radiation dosimetry based on <sup>111</sup>In or <sup>177</sup>Lu? **J Nucl Med**. 2005; 46(4):634-641.

Bander NH, Trabulsi EJ, Kostakoglu L, Yao D, Vallabhajosula S, Smith-Jones P, Joyce MA, Milowsky M, Nanus DM, Goldsmith SJ. Targeting metastatic prostate cancer with radiolabeled monoclonal antibody J591 to the extracellular domain of prostate specific membrane antigen. **J Urol**. 2003; 170:1717-1721.

## Selected Patents in which GBI Scientists Participated

Mohamed N, Casey L, Porter J, Wang X, Sesay M, Lee L. **Production of bispecific molecules using polyethylene glycol linkers**. Also patent pending filed with World, Canada, Australia, Japan, Europe and other countries.

Mohamed N, Casey L, Porter J, Wang X, Sesay M, Lee L. **Bispecific molecule comprising an anti-CRI antibody cross-linked to an antigen-binding antibody fragment**. Also patent pending filed with World, Canada, Australia, Japan, Europe and other countries.

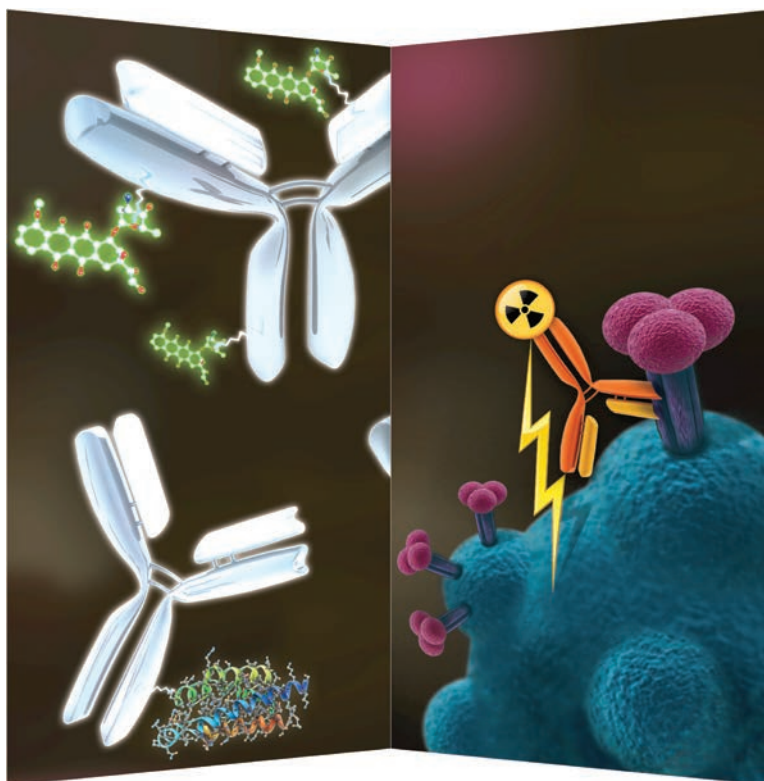


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